



# REPORT OF THE NOMINATING COMMITTEE

## 2010-2015 OFFICERS AND TRUSTEES

March 31, 2010

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**CONTENTS**

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<b>PART I</b>	<b>MEMORANDUM FROM THE NOMINATING COMMITTEE FOR OFFICERS AND TRUSTEES .....</b>	<b>4</b>
<b>PART II</b>	<b>LIST OF CANDIDATES BY POSITION .....</b>	<b>7</b>
<b>PART III</b>	<b>CANDIDATES' BIOGRAPHICAL INFORMATION</b>	
	<b>PAST PRESIDENT .....</b>	<b>9</b>
	<b>PRESIDENT .....</b>	<b>10</b>
	<b>TREASURER .....</b>	<b>12</b>
	<b>MEDICAL SCIENCES .....</b>	<b>14</b>
	<b>PHARMACEUTICAL SCIENCES .....</b>	<b>18</b>
	<b>PUBLIC .....</b>	<b>22</b>
	<b>AT-LARGE .....</b>	<b>24</b>
<b>PART IV</b>	<b>APPENDIX</b>	
	<b>EXCERPTS FROM THE USP CONSTITUTION AND BYLAWS PERTAINING TO THE NOMINATING COMMITTEE FOR OFFICERS AND TRUSTEES .....</b>	<b>31</b>





## PART I

### MEMORANDUM FROM THE NOMINATING COMMITTEE FOR THE 2010 – 2015 OFFICERS AND TRUSTEES

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

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## PART I. MEMORANDUM FROM THE NOMINATING COMMITTEE FOR OFFICERS AND TRUSTEES

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In accordance with the USP Constitution and Bylaws, in July 2009 René H. Bravo, M.D., President of the USP Convention, with the advice and consent of the Board of Trustees, appointed six members to the Nominating Committee for Officers and Trustees (NC-O&T). Committee members are listed following this memorandum, and the relevant provisions of the Bylaws relating to the NC-O&T are available as an appendix to this report.

The Committee conducted four teleconferences and one in-person meeting with additional communications via email throughout the process. The NC-O&T met via teleconference on September 11, 2009 to review the charge of the Committee, discuss USP's strategic direction for the 2010-2015 cycle, determine the qualifications and skills desired in Board candidates and set a timeline for the recruitment and evaluation of candidates. Careful consideration was given to the breadth of experience that would be needed to guide USP in its future endeavors. At the Committee's direction, USP staff launched a Call for Candidates, which was communicated to the Convention membership via a Member Memo on October 13, 2009. Individuals interested in volunteering for officer and trustee positions were directed to an online application that was accessible through the home page and Convention page of the USP website. Prospective candidates were also identified by USP management, current Board members, and other volunteers, all of which were presented to the NC-O&T for consideration.

On December 1, 2009, the Committee began assessing the candidate pool and determining a method for refining the list of candidates for final selection. As a result of this meeting, the Committee directed that selected individuals be contacted to assess their willingness to run and to gather additional details about the potential candidates' backgrounds and qualifications. This outreach was handled by EVP-CEO working on behalf of the Convention and at the direction of both its President as well as the NC-O&T. The NC-O&T met in person on January 11, 2010 to begin development of a final slate. The Committee met twice via teleconference during February to confirm candidates of interest and to complete their selections using a final USP staff report indicating candidate interest and qualification.

On behalf of the NC-O&T, USP staff contacted the selected candidates in February and March to notify them formally of their nominations and to assist them in preparing the background information that Delegates will find in Part IV of this report. Because of the broad skills and high level of expertise exhibited by all of the candidates, the NC-O&T decided not to subdivide the ballot by pairing candidates within the Medical Sciences, Pharmaceutical Sciences, or At-Large categories.

The NC-O&T is pleased and honored to present this slate of candidates for consideration by the Convention. The Committee encourages all USP Delegates to review all of the candidate information carefully, as the candidates who they select via ballot at Convention will have direct and primary responsibility for the organization and represent of the Convention membership between meetings.

Respectfully submitted,

Mary Anne Koda-Kimble, Pharm.D.  
Chair, Nominating Committee for Officers and Trustees



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**MEMBERS OF THE NOMINATING COMMITTEE FOR  
OFFICERS AND TRUSTEES**

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**USP CONVENTION PRESIDENT**

René H. Bravo, M.D., F.A.A.P., (ex-officio)

**CHAIR AND TRUSTEE REPRESENTING THE PHARMACEUTICAL SCIENCES**

Mary Anne Koda-Kimble, Pharm.D.

**COMMITTEE MEMBER AND TRUSTEE REPRESENTING THE MEDICAL SCIENCES**

D. Craig Brater, M.D., F.C.C.P.

**COMMITTEE MEMBERS REPRESENTING THE USP CONVENTION**

John Lisack, C.A.E., American Association of Pharmaceutical Scientists

Henri Manasse, Jr., Ph.D., D.Sc., American Society of Health-System Pharmacists

Deborah K. Walker, Ed.D., American Public Health Association





## PART II

### LIST OF CANDIDATES BY POSITION

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

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## PART II. LIST OF CANDIDATES BY POSITION

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### **PRESIDENT OF THE CONVENTION**

Timothy R. Franson, B.S. Pharm., M.D.  
Douglas E. Rollins, M.D., Ph.D.

### **TREASURER OF THE CONVENTION**

John E. Courtney, Ph.D.  
Amy Porter

### **TRUSTEE REPRESENTING THE MEDICAL SCIENCES**

Lisa A. Cooper, M.D., M.P.H.  
Mark R. Dybul, M.D.  
Robert A. Kelch, M.D.  
Robert M. Russell, M.D.

### **TRUSTEE REPRESENTING THE PHARMACEUTICAL SCIENCES**

Duane M. Kirking, Pharm.D., Ph.D.  
John W. Mauger, Ph.D.  
Mario Rocci, Jr., Ph.D.  
Marilyn K. Speedie, Ph.D.

### **TRUSTEE REPRESENTING THE PUBLIC**

Carolyn H. Asbury, Ph.D., Sc.M.P.H.  
Myrl Weinberg, C.A.E.

### **TRUSTEE AT LARGE**

Harvey E. Bale, Jr., Ph.D.  
Enriqueta Bond, Ph.D.  
Judith A. Oulton, R.N., M.Ed.  
Frank J. Sasinowski, M.S., M.P.H., J.D.  
Thomas R. Temple, R.Ph., M.S.  
Gail Wilensky, Ph.D.





## PART III

### CANDIDATES' BIOGRAPHICAL INFORMATION

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

**PAST PRESIDENT**  
**RENÉ H. BRAVO, M.D., F.A.A.P.**



Dr. René Bravo has served as President since 2007, after having served as an At-Large Trustee since the 2005 Convention. He has served as a USP volunteer, representing the California Medical Association since 1995 and as Chair of the Membership Committee from 2000 to 2005.

Dr. Bravo is a pediatrician who has lived and practiced pediatrics on the Central Coast of California since 1986. A graduate of the University of California, San Francisco School of Medicine, Dr. Bravo did his internship and residency at Stanford University Medical Center in Palo Alto.

Dr. Bravo started his medical career at the San Luis Medical Clinic, and later joined the Pediatric Associates Medical Group where he practiced for 9 years. In 2000, Dr. Bravo started his own medical practice in San Luis Obispo.

A longtime advocate for children and families, Dr. Bravo strives to see the quality of children's lives improved. He spent several years leading medical mission trips into the very remotest regions of rural Guatemala, working with children orphaned by civil war. He developed vaccination and pediatric care clinics in these primitive areas. In the local community, Dr. Bravo also directed and led the NICU (Neonatal Intensive Care Unit) at Sierra Vista in its very earliest years.

He is the Chief of Pediatrics at Sierra Vista Regional Medical Center and well as sitting on the hospital's governing board. He was the Chief of Staff at SLO General Hospital (San Luis Obispo).

Active on the Central Coast, Dr. Bravo has served on many community boards including leadership positions in the American Cancer Society, the Partnership for the Children of San Luis Obispo County and the San Luis Obispo County Foundation for Public Libraries (past-President). He is past Chairman of the State of California's Medical Drug Use Review (DUR) Board in Sacramento appointed by Governor Wilson to help design, develop and implement the nation's largest DUR program for the State's MediCal recipients.

Dr. Bravo is especially passionate about children's health issues and has served as President of the Partnership for the Children of San Luis Obispo County and assisted in the initial vision and development of the Clinic de Tolosa Dental Clinic in Paso Robles. He currently serves on the San Luis Obispo County Children and Families Commission (First Five Commission) established by the voters of California to administer the tobacco settlement funds. First Five has been a powerful vehicle to affect children's health and welfare as they work with various entities in the community. He has served on the Children's Leadership Council to create the Children's Center of SLO (Martha's Place) to assist in the identification, evaluation and treatment of children exposed to perinatal substance abuse.

He was the founding President of the Children's Health Initiative of San Luis Obispo County, bringing together a widespread coalition of private, public and government organizations to found and support a universal health care network for all children in this community.

At the statewide level, Dr. Bravo has recently served on the Blue Shield of California Corporate Advisory Council in San Francisco and on the Board of Directors of the California Medical Association (CMA) Foundation. He currently is on the Board of Directors of the CMA's Political Action Committee (CALPAC) in Sacramento. He is also past chair of the Pharmacy Technical Advisory Committee for the CMA. The San Luis Obispo County Board of Supervisors appointed Doctor Bravo to serve as physician representative to the CenCal Health, Santa Barbara- San Luis Obispo County Regional Health Authority which administers the state's Medicaid program.

Dr. Bravo is a Diplomate of the American Board of Pediatrics and a Fellow of the American Academy of Pediatrics.

A family man, Dr. Bravo lives in San Luis Obispo with his wife and their five sons.





## PRESIDENT

### TIMOTHY R. FRANSON, B.S. PHARM., M.D.

Dr. Franson currently serves as Senior Vice President, B&D Consulting (leader of regulatory affairs practice in the health and life sciences sector) providing strategic and operational advice for drug development, policy and related regulatory issues management. He is former Vice President of Global Regulatory Affairs/Drug Safety for Eli Lilly & Company. He also served as a member of Lilly Research Laboratories Policy Committee and Chair -Global Product Labeling Committee and as a member of Global Product Quality Committee. Prior to his work at Lilly, Dr. Franson was an Assistant Professor of Medicine (Infectious Diseases) and Hospital Epidemiologist at Medical College of Wisconsin (Milwaukee). Dr. Franson's professional interests include infectious diseases in the elderly (having served as former NIA/NIH RO-1 principal investigator); hospital epidemiology (device associated nosocomial infections); and antibiotic DUR.

Dr. Franson served on the Xavier University of Louisiana Board of Trustees from 2002-2008; Regulatory Advisory Board—Centres for Medicines Research International from 2003-2008; Pharmaceutical Research and Manufacturers Association (past chair of Clinical Steering Committee, past chair of GMP Task Force, past chair of FDA Staff Work Group, member-Regulatory Affairs Committee and co-chair of PDUFA-3 coordination/negotiations committee); Auburn University Harrison School of Pharmacy Dean's Advisory Committee; and Drake College of Pharmacy Advisory Committee. He is past chair Villages of Indiana Child Welfare Board of Directors and serves on the Executive Committee—Little Red Door Cancer Agency. He currently serves on the Board of Directors—Indiana State Museum Foundation; Myriad Pharmaceuticals Board of Directors; Quadraspec Board of Directors; and in the past on the State of Wisconsin Governors Task Force on AIDS (1984). Dr. Franson also served on American Association of Colleges of Pharmacy's Pharmaceutical Education Advisory Committee and the Association of American Medical Colleges-PhRMA Clinical Trials Forum.

Dr. Franson was named James Scholar—University of Illinois College of Medicine (1977-78); is a member of Rho Chi Honor Society—Drake University College of Pharmacy; earned Lilly Chairman's Ovation Award (2002); and was awarded Sagamore of the Wabash by Indiana Governor Mitchell E. Daniels Jr for community service

**Statement of Interest:** It would be a great privilege to serve the USP in this leadership role. My past experience as a practicing pharmacist and a consulting physician, with a long career in industry drug development management provided me extensive interactions with practice communities as well as regulators and policy makers. Those varied roles shaped my understanding of quality standards from multiple perspectives, and allows me to relate to issues from a broad range of constituencies. The next decade will likely bring many changes in new science and technology, which in turn demands thoughtful anticipation of evolving issues in quality standards and patient needs. Two key concerns to address in preparing USP for that uncertain future will be to engage young professionals in becoming our next generation of leaders and to effectively communicate the value which our collective expertise brings to 21<sup>st</sup> century patients.

**PRESIDENT**  
**DOUGLAS E. ROLLINS, M.D., PH.D.**

Dr. Rollins is currently Professor of Pharmacology and Toxicology, Adjunct Professor of Internal Medicine, and Associate Medical Director of the Utah Poison Control Center at the University of Utah. His primary responsibilities are teaching pharmacy and medical students, and pharmacology and analytical toxicology research. His current research is directed toward the development, evaluation, and application of biomarkers of drug ingestion and disease. He currently has research grants to study a serum biomarker of drug hepatotoxicity, a biomarker to monitor low-level cigarette smoking, and biomarkers of drug doping in sports. Continuing research interests are the disposition of drug of abuse and the development of analytical methods to detect their use. Dr. Rollins is also involved in curriculum improvement for pharmacy and medical students, in improving the doping control programs of several professional and amateur sports programs, and in advancing national forensic science standards.



Dr. Rollins served as a delegate to the USP Convention in 1995 representing the University of Utah Medical School. He has served as a member of the Board of Directors of the American Society of Clinical Pharmacology and Therapeutics. He currently serves on the Advisory Board for the Utah Poison Control Center, and from 2003 to 2006 was a member of the Board of Directors of the Sports Medicine Research and Testing Laboratory, a non-profit anti-doping laboratory located in Salt Lake City, Utah. During the Sydney Australia Olympic Games in 2000, Dr. Rollins served as an *ad hoc* member of the Medical Commission of the International Olympic Committee (IOC). He has been an active member of the Society of Forensic Toxicology, The International Association of Forensic Toxicologists, the American Society of Pharmacology and Therapeutics, and the American Association for the Advancement of Science. Dr. Rollins received the Lilly Achievement Award for leadership as a pharmacy student at Ohio State University where he was president of Rho Chi Pharmacy Honor Society. He has served on Grant Review Study Sections for the National Institute on Drug Abuse, and from 1994 to 1998 was a member of the National Board of Medical Examiners, writing pharmacology questions for medical licensure exams. From 1980 to 2000 he served as Medical Director of the Utah Poison Control Center. From 1998 to 2000 he was a Visiting Professor at Gifu University in Gifu Japan. From 1998 to 2000 Dr. Rollins was Interim Chair of the Department of Pharmacy Practice of the University of Utah College of Pharmacy. From 1998 to 2002 he served as Medical Director for the Doping Control Program for the 2002 Winter Olympic Games in Salt Lake City. In this capacity he worked with the Medical Commission of the International Olympic Committee (IOC) and supervised a paid and volunteer staff of nearly 300. From 1983 to 2000 Dr. Rollins served as Director of the Center for Human Toxicology at the University of Utah and from 2006 to 2009 was Executive Director of the Sports Medicine Research and Testing Laboratory, one of two anti-doping laboratories in the United States accredited by the World Anti-Doping Agency.

**Statement of Interest:** Beginning as an undergraduate in pharmacy, through graduate school in pharmacology and medical school, through postdoctoral work at the National Institute of Health, and continuing for nearly thirty years as a physician, research scientist, and teacher of pharmacy and medical students, I devoted my career to increasing knowledge and improving the utilization of pharmaceuticals. I will bring a broad understanding of pharmaceuticals, a large exposure to national and international sciences, and a wide variety of leadership experiences to the USP Board of Trustees. I will work to assure USP's products and services continue to meet the needs of its constituencies and that USP remains a financially healthy organization. As healthcare evolves, being a member of the USP Board of Trustees will provide me an opportunity to work within an organization that strives to improve world-wide public health through ensuring the quality, safety and benefits of pharmaceutical and nutritional products.





**TREASURER**  
**JOHN E. COURTNEY, PH.D.**

Dr. Courtney is currently the Chief Executive Officer for the American Society for Nutrition (ASN). He is responsible for working effectively with ASN's board and members (consisting of the world's top researchers and clinical nutritionists), industry and governments in over 100 countries around the world, to advance the knowledge and application of nutrition for the sake of humans and animals. He is responsible for facilitating the development and implementation of ASN's Strategic Roadmap, aligning resources to support mission related activities, and ensuring the continuing growth and financial success of the pre-eminent nutrition research society in the world.

Dr. Courtney's research and professional interests include advancing public health worldwide through nutrition research and practice. He holds a Ph.D. and an MBA with over 20 years of successful Chief Executive Officer, Chief Financial Officer, and senior level executive experience successfully working with voluntary health organizations, professional membership academic societies and academia in developing and successfully executing strategies to grow and advance the organization in pursuing its mission related activities.

During his successful experience as chief executive at American Society for Nutrition and the Clinical Research Forum and as Chief Financial Officer at the American Diabetes Association, Dr. Courtney has worked on many of the same issues relevant to USP, including healthcare delivery and patient safety, drug information and standards related to healthcare delivery and product quality. Dr. Courtney's board experience includes serving on the following Boards: The American Society for Nutrition, The American Society for Nutrition Research Foundation, The Clinical Research Forum, The Clinical Research Forum Research Foundation, Leadership Cares, and serving as a member of the American Society of Association Executives CEO Roundtable.

As a seasoned Chief Financial Officer for a 200+ million dollar non-profit organization, he has a thorough understanding of the requirements necessary to successfully perform the responsibilities of Treasurer of USP. In addition to his service as Executive Officer of the American Society for Nutrition, Dr. Courtney has served as Founding Board Treasurer of the ASN Research Foundation, Chief Executive Officer of the Clinical Research Forum and Clinical Research Forum Research Foundation, and Chief Financial and Administrative Officer for the American Diabetes Association. He has been a frequent speaker interacting with Congress, governmental agencies, international organizations, and professional societies including Financial Roundtables and other meetings dedicated to ensuring the appropriate financial oversight of non profit organizations.

**Statement of Interest:** I am honored to be considered as a candidate for the Treasurer position of USP. My successful Chief Executive and Chief Financial experience developing, executing and growing programs to advance the mission and financial health of organizations will be helpful in facilitating the development and execution of the USP Board's Strategic Plan and ensuring the continuing success of USP. USP's extremely important work, its stellar reputation, its pre-eminent membership and outstanding staff played a role in my desire to volunteer my time and energy on behalf of USP. Unfortunately, I cannot join you for the candidate forum as my American Society for Nutrition Board meeting and Annual Scientific Sessions are taking place in Anaheim at this time, but please let me reinforce to you my passion and commitment to successfully serving the membership as your next Treasurer. Together we can outline a vision for the next 5 years.

**TREASURER  
AMY PORTER**

Amy Porter is the Executive Director and Chief Executive Officer of the National Osteoporosis Foundation. In this capacity, she is responsible for managing and leading the nation's premier osteoporosis organization.

Ms. Porter excels at fostering nonprofit organizational cultures that support positive growth through the alignment of creativity and strategy, which results in achieving and surpassing organizational revenue and financial goals and producing programmatic growth and successful programmatic outcomes.

Ms. Porter was the Executive Director of the Foundation for the National Institutes (FNIH) for eight of its first fourteen years since inception in 1996. She is largely responsible for FNIH's current stature as an innovative, pioneering convener of public-private partnerships in biomedical research. During her tenure as Executive Director, she led the growth of the organization from less than ten employees to its current size of nearly 50 employees (including contract employees), and increased its annual revenues from \$12 million to \$80 to \$90 million. While at the FNIH, Ms. Porter spearheaded the establishment of the Biomarkers Consortium, a unique public-private partnership that includes the FDA, the NIH and major pharmaceutical companies; the development of the Alzheimer's Disease Neuroimaging Initiative (ADNI), NIH's largest public-private partnership on brain research; and administered \$200 million in grants in the Grand Challenges in Global Health initiative.

In 2005, Ms. Porter received the NIH Director's Award from the Director of the Clinical Center for her efforts to raise \$10 million in funds to build the Edmond J. Safra Family Lodge in support of the families of patients at the NIH Clinical Center. She received The University of Akron's highest honor, the Honorary Alumni Award, in 2009 for her achievements in the nonprofit sector.

**Statement of Interest:** My experience in developing new paradigms of participatory, transparent partnerships, involving government agencies and private partners, employed the same values USP expresses in its work. My work at the FNIH has put important data and information into the public domain; has linked partners with shared goals in ways that produce results for all, and fostered dramatic revenue and financial growth for the FNIH. Now at the National Osteoporosis Foundation, my goal is to bring that same level of success and recognition, while amplifying the voice of patients who experience this disease. I believe my approach and philosophies – coupled with my experience would help USP seek, recognize and capture opportunities for increased revenue generation and further USP's financial success. I would treasure the opportunity to be involved with this important and impressive organization.





## MEDICAL SCIENCES TRUSTEE

LISA A. COOPER, M.D., M.P.H.

Dr. Cooper is a board-certified general internist, health services and outcomes researcher, medical educator, and a member of Johns Hopkins Hospital Medical Staff. She is Professor of Medicine, Johns Hopkins University School of Medicine; Professor of Epidemiology, Health Policy & Management, and Health Behavior & Society, Johns Hopkins Bloomberg School of Public Health; and Professor of Nursing, Johns Hopkins School of Nursing.

Dr. Cooper's professional interests include racial, ethnic, and social class health disparities; global health; quality of primary care delivery; patient-centered care; patient-physician communication; treatment of depression and cardiovascular disease. She served on the Board of Trustees for Howard County General Hospital in Columbia, MD from 2003-2006 and has served on the Johns Hopkins Medicine Diversity Steering Committee since 2006. Dr. Cooper currently serves on the Steering Committee, Practice-Based Research Network Resource Center, Agency for Healthcare Research and Quality and Underserved Advisory Committee, American Board of Internal Medicine. She previously served on the National Advisory Committee, Robert Wood Johnson Foundation Program on Depression in Primary Care; the Advisory Panel, Strategies to Improve the Quality of Health Care Services in the United Kingdom and the United States, The Nuffield Trust and The Commonwealth Fund; and National Advisory Committee, Finding Answers: Disparities Research for Change, Robert Wood Johnson Foundation. Dr. Cooper was elected as a member of the American Society for Clinical Investigation (ASCI) in 2005, was selected as a MacArthur Fellow in 2007, and was elected to the National Academy of Sciences Institute of Medicine in 2008. She earned the Herbert W. Nickens Award for exceptional contributions to cultural diversity in medicine from the Society of General Internal Medicine in 2006 and earned the George Engel Research Award from the American Academy on Communication in Healthcare in 2008. She was elected to the Delta Omega Public Health Honorary Society in 2008 and elected to Fellowship in the American College of Physicians in 2009. Dr. Cooper has served a number of leadership roles for the Society of General Internal Medicine (SGIM), including co-Chair, Health Services Research Abstract Selection Committee; Chair, Herbert W. Nickens Award Selection Committee; Chair, Disparities in Health Research Abstract Selection Committee; Chair, Precourse Committee, Annual Meeting; and Chair, Scientific Review Committee, 2004 Annual Meeting.

Dr. Cooper was recognized by the Mental Health Association of Maryland Metropolitan Baltimore Branch with the Community Partnership of the Year Award in 2000. She was an honoree at Bethel African Methodist Episcopal Church's "Women Who Make a Difference and Change the World" Celebration and received the Trailblazer Award, Paying Tribute to Maryland's Philanthropic African Americans in Medicine, Associated Black Charities, Baltimore, Maryland. She was listed as one of MSNBC.com TheGrio's 100 History Makers in the Making in February 2010.

**Statement of Interest:** I am a physician trained in internal medicine and public health. I spend most of my time conducting clinical research. I also deliver primary care to patients and teach health professional and public health students. My interests in reducing global inequities in health and access to care are long-standing; I grew up in Liberia, West Africa. My research focuses on understanding barriers to care and mechanisms for disparities in healthcare quality, including clinician communication and cultural competence. I have tested interventions to improve quality of care and reduce disparities in care. I have also used participatory approaches to engage clinicians, patients, community members, professional stakeholder groups, and policy-makers in all aspects of my research, including efforts to translate research findings into practice. I would be honored to help USP maximize its impact on global health through public standards to ensure the safety, quality, and benefit of medicines and foods.



**MEDICAL SCIENCES TRUSTEE**  
**MARK R. DYBUL, M.D.**

Ambassador Mark R. Dybul co-directs the Global Health Law Program at Georgetown University Law Center's O'Neill Institute for National and Global Health Law, where he is also a Distinguished Visiting Scholar. He is the inaugural Global Health Fellow of the George W. Bush Institute and serves as the Managing Director of the Office of the United Nation Special Envoy for Malaria. Ambassador Dybul served as the United States Global AIDS Coordinator from 2006 to the end of the George W. Bush administration. In that role, he led the implementation of the President's Emergency Plan for AIDS Relief (PEPFAR), the largest international health initiative in history for a single disease.

Ambassador Dybul oversaw the United States government engagement in the Global Fund to Fight AIDS, Tuberculosis and Malaria and was the Chair of the Finance and Audit Committee. He also served as chair of the Joint United Nations Programme on HIV/AIDS' coordinating board and as a member of the board of trustees of the Woodrow Wilson International Center for Scholars. Prior to assuming the post of Ambassador, he was Acting, Deputy and Assistant Coordinator, and was a member of the Planning Task Force that created PEPFAR. He also led President Bush's International Prevention of Mother and Child HIV initiative at the Department of Health and Human Services (HHS), was the Executive Secretary for HHS guideline for adult and adolescent HIV therapy and was a member of the writing committee for the World Health Organization's guidelines on the use of antiretroviral therapy. At HHS, Ambassador Dybul served as the Assistant Director for Medical Affairs at the National Institute of Allergy and Infectious Diseases and the National Institutes of Health, and was the principal investigator of basic and clinical research with a particular emphasis on HIV treatment in Africa. He is well published in scientific and policy literature, has received several honorary degrees and significant awards, and has served on numerous national and international boards.



Ambassador Dybul received his A.B. in philosophy and M.D. from Georgetown University before completing a residency in Internal Medicine at the University of Chicago Medical Center in 1992 and a fellowship in Infectious Diseases from the National Institute of Allergy and Infectious Diseases in 1995.

**Statement of Interest:** Dr. Dybul's statement of interest will be provided at a later date.



**MEDICAL SCIENCES TRUSTEE**  
**ROBERT P. KELCH, M.D.**

Dr. Robert Kelch is Special Advisor to the Executive VP for Medical Affairs at the University of Michigan and Executive Vice President for Medical Affairs Emeritus, University of Michigan. His areas of interest include neuroendocrine regulation of human growth and sexual maturation, and the management and development of health care delivery systems and health care insurance products including managed care products.

Dr. Kelch currently serves as the Chairman of the Board of Altarum Institute, as a board member for Blue Care Network of Michigan, and a member of the Blue Ridge Academic Health Group. He previously served as Chairman of the Board for the American Board of Pediatrics, President of the Society for Pediatric Research, President of the Federation of Pediatric Organizations, and President of the Midwest Society for Pediatric Research. He was the Chair of the Department of Pediatrics at the University of Michigan from 1981-1994, Dean of the University of Iowa College of Medicine from 1994-2003, Vice President of Health Affairs at the University of Iowa from 2001-2003, and Executive Vice President for Medical Affairs at the University of Michigan from 2003-2009.

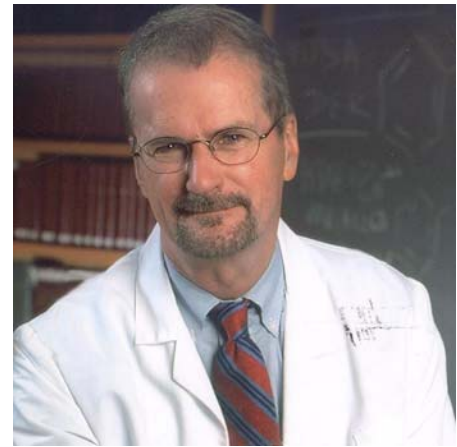
Dr. Kelch has received the following awards and recognitions:

- Who's Who in America – 1980 -current
- The Best Doctors in America - 4th Edition – current
- Member, American Society for Clinical Investigation, 1982 - current
- The Surgeon General's Certificate of Appreciation, Antonia C. Novello, M.D. (1993)
- University of Iowa Foundation Distinguished Fellow (1994)
- Member, Institute of Medicine of the National Academy of Science, 1996 - current
- Iowa Medical Society's Merit Award (2000)
- Huntington's Disease Society of America, Distinguished Leadership Award (2001)
- Distinguished Service Member, AAMC, 2003
- MWSPR Founder's Award, 2004
- Who's Who in Medicine and Healthcare, 2004-05 Edition
- Who's Who in Science and Engineering, 2005-06 Edition
- Federation of Pediatric Organizations, Joseph W. St. Geme, Jr. Leadership Award, 2005
- Dictionary of International Biography, 33<sup>rd</sup> Edition
- University of Iowa Carver College of Medicine Distinguished Alumnus Award for Friendship, 2006

**Statement of Interest:** For the past 43 years, I have been working in medical centers in a series of positions with steadily increasing responsibilities, including high level positions in two large Midwestern academic health systems. After completion of my pediatrics residency and pediatric endocrinology fellowship, I was an active clinician, educator, and NIH-funded investigator studying the neuro-endocrine regulation of human growth and sexual maturation. I have served in leadership positions in many national pediatric organizations and have devoted considerable effort toward improving health care for children and the general population. I am currently Chairman of the Board of the Altarum Institute, an organization dedicated to improving the health of our citizens through systems analysis and research. I have considerable experience in the development of educational, research, and clinical standards. Moreover, I feel that the breadth of my experience and leadership accomplishments will be beneficial to the USP and I would be honored to serve on this most important standard-setting organization.

**MEDICAL SCIENCES TRUSTEE**  
**ROBERT M. RUSSELL, M.D.**

Dr. Russell is Professor Emeritus in Medicine and Nutrition, Tufts University and President of the American Society for Nutrition, a professional scientific society of over 4000 members. He also serves as a Special Expert for the National Institutes of Health, advising and implementing programs for the Office of Dietary Supplements, Office of the Director. Dr. Russell has thirty years of experience as a researcher in nutrient metabolism and biology. His professional interests include application of evidenced-based reviews and the application of utility analysis in nutrition policy and decision making.



Dr. Russell served on the USP Council of Experts Committee on Nutrition and Electrolytes from 2000-2004. He is a current member of the Nestlé Foundation, Lausanne and also of the Golden Rice Humanitarian Board, Basel. He previously served as a Trustee, International Life Science Institute and as Chair of the Food and Nutrition Board, IOM, National Academy of Science.

Dr. Russell has received the following major awards:

- 2005 DSM Human Nutrition Award for Research Accomplishment
- 2007 Fellow, American Society for Nutrition (ASN)
- 2007 National Associate of the National Research Council of the National Academies of Science.
- 2009 David Kritchevski Distinguished Career Award, ASN
- 2010 Atwater Award, United States Department of Agriculture

Dr. Russell has also held positions as Chairman of Panel on Micronutrients, Food and Nutrition Board, Institute of Medicine, National Academy of Science; Director, USDA Human Nutrition Research Center on Aging, Tufts University; Chair, United States National Committee to the International Union of Nutritional Sciences, Food & Nutrition Board, IOM; Chair, Committee on Mineral Requirements for Cognitive & Physical Performance of Military Personnel, Food & Nutrition Board, IOM; and on the UNICEF Consulting Team-Southern Iraq.

**Statement of Interest:** I believe that my combined expertise in the areas of nutrition and medicine will strengthen the efforts of USP in this growing and vital area of scientific and health interest. Nutrition is the foundation of our health, and poor nutrition is related to all of the major chronic diseases of our society. I have deep leadership experience and have worked with all sectors: academia, government (FDA, USDA, NIH, FTC) and industry to solve nutritional problems of public health importance. I have been involved with many international nutrition projects for UNICEF and the World Health Organization, working primarily in the Middle East and Asia. International standards are needed for food and traditional medicines (dietary supplements in the US), and this is something that USP can contribute greatly toward in the years to come. I hope to be able to add to USP's public health impact over the next several years.



**PHARMACEUTICAL SCIENCES TRUSTEE**  
**DUANE M. KIRKING, PHARM.D., PH.D.**

Dr. Kirking is Professor Emeritus, College of Pharmacy, University of Michigan; Research Scientist Emeritus, School of Public Health, University of Michigan; and Senior Advisor; Center for Medication Use, Policy and Economics; University of Michigan. His career has been devoted broadly to evaluating and improving the use of medications. Of particular interest is medication undertreatment and underuse. In addition to quantifying medication use problems, Dr. Kirking has conducted research to understand the reasons for those problems, including from the system, provider and patient perspectives. This has led to the design of interventions to reduce these problems, including those using new technologies. At a system level he has advocated health policy changes that facilitate expanded and improved medication payment.

Dr. Kirking has served on the USP Board of Trustees since 2005, serving as Board Chair since 2008. He served on the USP Medicare Part D Model Guidelines Committee in 2004; USP Expert Committee on Therapeutic Decision Making from 2000-2005; and USP Advisory Panel on Drug Utilization Review, 1990-2000. Dr. Kirking was USP Convention Delegate for University of Michigan College of Pharmacy during the 1995, 2000, and 2005 Convention Meetings. He was also a USP Scholar-in-Residence, 1993-1994. Dr. Kirking served on the American Pharmacists Association's Board of Trustees from 1998-1999 and has served on University of Wisconsin School of Pharmacy's Board of Visitors since 2007. He served on Michigan Department of Social Services, Medicaid Drug Use Review Board from 1992-2008, serving as Vice-chair from 2003-2006 and Chair from 2006-2008.

Dr. Kirking was awarded the Research Achievement Award in the Pharmaceutical Sciences by the American Pharmacists Association Academy of Pharmaceutical Research and Science; is a Fellow, American Pharmacists Association Academy of Pharmaceutical Research and Science; and was co-author of the paper awarded 2000 Best Published Paper Award, Economic Social and Administrative Sciences by the American Pharmacists Association. He won the Jack L. Beal Postbaccalaureate Alumni Award, Ohio State University College of Pharmacy; won a Citation of Merit, University of Wisconsin School of Pharmacy; was named to *Marquis Who's Who in American Education*, 7<sup>th</sup> and 8<sup>th</sup> editions; and is a member of Rho Chi Pharmacy Honor Society. Dr. Kirking has held various leadership positions with the American Pharmacists Association, including Presidential Officer (with elect and immediate past offices), Academy of Pharmaceutical Research and Science (1997-2000). During his academic career at the University of Michigan, major leadership positions included Department Chair (1999-2004) and Director, Center for Medication Use, Policy and Economics (2005-2007).

**Statement of Interest:** Knowledge of scientific issues concerning USP's standards for quality medicines and foods is essential. Second is a vision, tempered by the realities of today's fiscal and political environments, for what activities are vital to ensuring that USP's core functions are supported while new opportunities are pursued as appropriate. Third is an openness and ability to work with other Board members and staff in developing achievable goals based upon a strategic plan. This includes making difficult decisions about which activities should be conducted, amidst a sea of worthy opportunities. Finally, given increasing demands of Board membership, members must be able to make a substantial commitment of time.

I have had the opportunity to help guide USP's growth in scope and into an organization with an international reach. I believe I have the experience that can continue to benefit USP and provide me with satisfaction that I am contributing to its success.

**PHARMACEUTICAL SCIENCES TRUSTEE**  
**JOHN W. MAUGER, PH.D.**

Dr. Mauger is Professor, University of Utah College of Pharmacy and Associate Vice President for Health Sciences. As associate vice president he is responsible for special projects under the aegis of the Senior Vice President for Health Sciences at the University of Utah Health Sciences Center.



Research interests include: 1) solubility of pharmaceutical compounds in co-solvent systems and 2) application of fluid mechanical principles to characterize the performance of the USP dissolution methodologies. Research entitled “Fluid and Particle Laser Doppler Velocity Measurements and Mass Transport Predictions in the USP Paddle Dissolution Apparatus” is recognized for its importance in characterizing the performance of USP dissolution methods. Professional interests include: 1) service to organizations that promote health literacy, 2) service to organizations that address the need for quality medicines and foods, 3) pharmacy education, and 4) contributions of the arts and sciences to society.

Dr. Mauger has served on the USP Biopharmaceutics Expert Committee, USP Board of Trustees, USP Board Executive Committee, and the Board of the American Council on Pharmaceutical Education. He is also a member of the Editorial Advisory Board for the Journal *Pharmaceutical Development and Technology*, the Huntsman Cancer Center Advisory Board, University of Utah Addiction Center Advisory Board, BIRCH (Building Interdisciplinary Careers in Women’s Health) Advisory Board, and Utah Poison Control Center Advisory Board.

Dr. Mauger has received the following honors and has held several leadership positions:

- Elected Fellow of the American Association for the Advancement of Science
- University of Utah College of Pharmacy Weaver Medal Award for Sustained Leadership and Commitment to Academic Excellence
- Douglas Glover Endowed Professorship
- Former Chair, USP Board of Trustees (2005-2008)
- Past President and Vice President of the Board of the American Council On Pharmaceutical Education
- Former Dean, University of Utah College of Pharmacy
- Former Co-Director of the Utah Addiction Center
- Former Chair, Department of Pharmaceutical Sciences, University of Nebraska Medical Center

**Statement of Interest:** An overarching qualification for Board membership is an unequivocal commitment to USP’s core mission of improving health through public standards that ensure quality and safety of medicines, foods and dietary supplements. Other important qualifications include the experience and willingness to act with unquestioned integrity and subordinate other interests when acting on behalf of USP, steward USP resources effectively and efficiently, provide fiscal oversight, participate in strategic planning and organizational direction, act as an advocate, and commit time and effort to board activities.

I am interested in serving as a member of the USP Board of Trustees in order to participate in strategic and tactical decisions that will support and strengthen the core mission of USP as an authoritative science-based organization. This mission continues to increase in importance in the face of world-wide distribution of drugs and foods that present opportunities for contamination and adulteration, with great risk to the public.



## PHARMACEUTICAL SCIENCES TRUSTEE

MARIO L. ROCCI, JR., PH.D., F.C.P.

Dr. Rocci is Executive Vice President at ICON Development Solutions, a Division of ICON plc, a contract research organization with over 7,000 employees worldwide. He has complete responsibility for bioanalytical and biomarker services globally, and serves on the Executive Team of the Division which performs early clinical drug development. His responsibilities include managing laboratories located in Whitesboro, NY, Manchester, UK and Oxford, UK and a staff of approximately 150 scientists, quality assurance professionals and support staff.

Dr. Rocci's research interests include: improving the therapeutic use of drugs; phenotypic probes of drug metabolizing enzyme activity and mass spectrometry; and various immunology-based analytical platforms to analyze drugs and biologics from biological matrices in support of drug research and development efforts.

Dr. Rocci's commitment to pharmaceutical science is reflected in his service as: Chairman, Board of Directors, Product Quality Research Institute, Vice President, Bureau (Board of Directors), International Pharmaceutical Federation (FIP), and previously as President, American Association of Pharmaceutical Scientists (AAPS). He has also served in other leadership capacities for AAPS including on the Executive Council (Board of Directors) for two terms. In addition, Dr. Rocci is a member of the Strategic Planning Task Force, American Society for Clinical Pharmacology and Therapeutics (ASCPT), is Congress Chair for FIP/AAPS Pharmaceutical Sciences World Congress 2010, and serves on the Editorial Advisory Board for The AAPS Journal. He is the current Chair of National Industrial Advisory Council, School of Pharmacy and Pharmaceutical Sciences, SUNY Buffalo, and former Chair Task Force On Science, American Society of Health-Systems Pharmacists (2008). He has served as an Expert and Executive Member of the Board of Pharmaceutical Sciences, International Pharmaceutical Committee and has held numerous Committee Chair positions with AAPS over the past two decades.

Dr. Rocci has been recognized broadly in the community: Willis G. Gregory Memorial Award, School of Pharmacy and Pharmaceutical Sciences, SUNY at Buffalo (2009), AAPS Distinguished Service Award (2006), Fellow, American College of Clinical Pharmacology and is a member of Sigma Xi Honorary Research Society and Rho Chi Honor Society.

**Statement of Interest:** First of all, I wish to apologize for not being present at the USP Convention, but two previous speaking commitments prevented my participation. I hope that my 30+ years of experience in pharmacy and pharmaceutical science, which has been broad-based and relevant to USP's focus for the future, resonate with delegates. I also have extensive executive level management experience and first-hand knowledge about leading professional organizations, including strategic planning and implementation of approaches to achieve strategic goals. I have been very successful in creating focused visions that have been progressive, ambitious (but achievable) and fiscally responsible and have had substantial experience in "turn around" and "refocusing" situations. I believe these experiences would be desirable for a USP Board member, and I would be honored to serve, if elected, as a team member committed to positioning USP within what I consider to be a very challenging future landscape.

**PHARMACEUTICAL SCIENCES TRUSTEE**  
**MARILYN K. SPEEDIE, PH.D.**

Dr. Speedie is Dean, University of Minnesota College of Pharmacy. Her responsibilities include developing the college's education, research and clinical practice missions and working with the profession to enhance pharmacy's ability to meet the health care needs of the state. Her personal research interests are in the area of biotechnology: microbial biotransformation, regulation of antibiotic biosynthesis, production of recombinant proteins, and enzymology. However, her interests extend broadly into drug discovery and development. Her professional interests are in how pharmacists can work with other professionals to better serve the health of patients nationally and globally.



Dr. Speedie's USP service includes:

- Member-at-large, USP Convention, 2000
- Delegate for University of Minnesota College of Pharmacy 2002-present
- Member, Council of Experts Biotechnology and Natural Therapeutics/Diagnostics Committee, 2000-2005
- Member, Resolution 18 Committee, 2003-2005
- Chair, Resolutions Committee for 2005

She has also served as Member, Biorganic and Natural Products Study Section, NIH from 1992- 1996; Member, Association of Academic Health Centers, Interprofessional Workforce Taskforce from 2005-2006; Member, Commission on Credentialing, American Society of Health System Pharmacy from 1999-2003; Member, Board of Directors for the National Institute for Pharmaceutical Technology and Education; and Board of Directors, American Association of Colleges of Pharmacy, 2000-2004 and 2005-2008

Dr. Speedie has earned the following awards and recognitions:

- President, American Association of Colleges of Pharmacy, 2006-07
- Paul Dawson Biotechnology Award, American Association of Colleges of Pharmacy, 1994
- Fellow, American Association of Pharmaceutical Scientists
- Harold R. Popp Award, Minnesota Pharmacists Association
- Hugh Kabat Award, Minnesota Society of Health-System Pharmacy
- 2010 Career Achievement Award, Kappa Epsilon Fraternity

**Statement of Interest:** Twenty-one years of my career was spent as a scientist and faculty member doing research in biotechnology related areas (microbial biotransformation, antibiotic biosynthesis, production of recombinant proteins) which gave me a strong science grounding. Subsequently, I have had 14 years of leadership experience as dean of the University of Minnesota College of Pharmacy, which has enabled me to use my science background to build a strong research focus for the college while developing expertise in professional and interprofessional education and advancing pharmacists' ability to care for the health of patients.

My previous experience with USP has impressed me with the value USP brings nationally and globally in addressing worldwide issues in health care including access to safe, high quality medications and the promotion of their optimum use. I believe I can use my science background combined with my professional background to contribute to USP's continued accomplishments.





**PUBLIC TRUSTEE**  
**CAROLYN H. ASBURY, PH.D., SC.M.P.H.**

Carolyn Asbury works to address public health initiatives to improve access to health care, especially medical drugs. She conducts drug policy research, translates findings into public policies, develops foundation-led public health initiatives, and assists non-profit health organizations undertake financially feasible strategic plans. She is currently senior consultant to the Dana Foundation, which supports clinical neuroscience and immunology research and translates results for the public; and she undertakes drug policy research as a Senior Fellow at the University of Pennsylvania's Leonard Davis Institute for Health Economics. She has served as USP's Public Trustee from 2005-2010.

Dr. Asbury earned a master of science in public health at Johns Hopkins, a doctorate in health systems at the Wharton school, and undertook postdoctoral training at the UCSF Institute for Health Policy Studies. She combines these disciplines in her work. Her research focuses on “orphan”—medically important but commercially unattractive—drugs and biologics, including those for rare diseases, children, women of child-bearing age, addiction treatment, and vaccines and drugs needed in developing nations. Translating this research into policy, she served as a Congressional consultant on the 1983 Orphan Drug Act, where she helped to shape the law's market incentives and regulatory changes that have increased development and market availability of rare disease drugs tenfold. Her work is widely published in journals (including the *Annals of Internal Medicine* and *JAMA*) book chapters, and a book: *Orphan Drugs: Medical vs. Market Value*, reviewed in *Science* and other journals. Her foundation-led initiatives prior to Dana, at the Robert Wood Johnson Foundation and then as director of Health and Human Services at the Pew Charitable Trusts, led to several innovations. She designed a program that diversified dementia care and respite services from center-only models to a wide array of community and home-based resources that increased providers nationally from 20 to more than 5,000. She developed a 10-year program to improve critical care prognoses and decision-making by physicians, patients and their families, cited by *Medicine and Health* in 1996 as one of the year's ten most important health care contributions. A medical malpractice program featured efforts to reduce medication errors. Her foundation work resembles that of USP, working with volunteer scientific experts. Additionally, she has evaluated foundation efforts to stimulate availability of pharmaceuticals in developing nations, and advised the pharmaceutical industry on international drug donation programs. Dr. Asbury has chaired the Board of the non-profit National Organization for Rare Disorders (NORD) which leads policy initiatives and administers a Medication Assistance Program that enables people with rare diseases who are uninsured, underinsured, or unable to afford co-payments to access needed treatment. She designed and chaired the first national conference on Determining the Feasibility and Desirability of Therapeutically Equivalent (“Generic”) Biologics, and currently serves on an Institute of Medicine Committee on Accelerating Rare Disease Research and Product Development. As Board Chair of the Treatment Research Institute, she spearheaded efforts to address substance-associated complications encountered in diagnosing and treating common diseases. Locally, she chairs the College of Physicians of Philadelphia's Section on Public Health and Preventive Medicine, and in June will become a College Trustee.

**Statement of Interest:** USP fulfills an essential public health function in a complex global economy. Through the work of its Expert Committees and staff, USP's standards assist manufacturers and the government in protecting the public, as dramatically illustrated by its leadership in averting further public health risks from adulterated glycerin and contaminated heparin. USP also is increasingly called upon to guide public policy, as evidenced by its role in the Medicare Model Guidelines. I have been fortunate to serve on the Board as the Public Representative, advising on its domestic and global activities, on acquiring the *Food Chemicals Codex*, and on its human resource and strategic planning initiatives. I would welcome the opportunity to continue to provide fiduciary and strategic guidance in support of USP's vital mission.



**PUBLIC TRUSTEE**  
**MYRL WEINBERG, C.A.E.**



Myrl Weinberg has served as president of the National Health Council (NHC) since 1996. NHC brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. NHC membership includes professional and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, and biotechnology companies. NHC's core membership includes approximately 50 of the nation's leading patient advocacy groups, ranging in size from the very large (such as the Alzheimer's Association, American Cancer Society, American Heart Association, and American Diabetes Association) to the small (including the Myasthenia Gravis Foundation, Sjögren's Syndrome Foundation, and Spina Bifida Association).

Ms. Weinberg's career has focused on health, medical research, long-term care, social security, and related issues that affect people with chronic diseases and disabilities and their family caregivers. Before joining the NHC, she held numerous managerial positions at the American Diabetes Association, including serving as Vice President for Corporate Relations and Public Affairs. Ms. Weinberg pursued advanced graduate study at Purdue University and holds an MA in Special Education from George Peabody College and a BA in Psychology from the University of Arkansas. Ms. Weinberg is a member of the American Society of Association Executives (ASAE) and has served on ASAE's Board of Directors, Joint Finance Committee, Ethics Task Force, and Fellows Nominating Committee. She was named an ASAE Fellow in 2007. The ASAE Fellows program recognizes individual accomplishments and contributions to the profession of association management. She has a long history of board and committee service, including current membership with U.S. Department of Health and Human Services (HHS) National Advisory Council for Healthcare Research and Quality, National Library of Medicine Board of Regents' Working Group on Clinical Trials, Center for Information and Study on Clinical Research Participation Advisory Board, Robert Wood Johnson Foundation's Aligning Forces for Quality Program National Advisory Committee, Roche International Genetics Science and Ethics Advisory Group and Clinical Research Ethics Advisory Group, Coalition Against Major Diseases Coordinating Committee, Governing Board of the International Alliance of Patients' Organization (IAPO), Community Health Charities Board of Directors, Independent Sector (IS) Nonprofit Sector Programs and Practice Committee, and Better Business Bureau Wise Giving Alliance Board of Directors and its Panel on Charity Effectiveness. She is a former member of the HHS American Health Information Community's Consumer Empowerment Workgroup, Institute of Medicine (IOM) Committee to assess how research priorities are established at NIH, National Research Council/IOM Committee on the Organizational Structure of NIH, IOM Committee on Improving the Organization of the U.S. Department of Health and Human Services to Advance the Health of Our Population, IOM Committee on Clinical Trial Registries, IOM Health Sciences Policy Board, AcademyHealth Coalition for Health Services Research Board, and FasterCures' Task Force on NIH's Intramural Research Program.

**Statement of Interest:** If elected to the USP Board of Trustees, I would bring to the Board and USP 20 years of leadership experience in health care non-profit associations and the representation of an organization that covers the full breadth of the health care community. Under my leadership at the NHC, we developed and enhanced our Standards of Excellence™ Certification Program. The Standards were adopted by the NHC Board to ensure that patient advocacy organization members maintain the highest levels of efficiency, accountability, transparency, and public stewardship. In addition to my work in the U.S., I was instrumental in the creation of the International Alliance of Patients' Organizations (IAPO) and am completing my term as Immediate Past Chair of the Governing Board. IAPO is a unique global alliance that represents patients of all nationalities across all disease areas and promotes patient-focused health care around the world. I greatly appreciate the nomination and would welcome the opportunity to serve.





**AT-LARGE TRUSTEE**  
**HARVEY E. BALE, B.A., M.A., PH.D.**

Dr. Bale is the former Director General of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), based in Geneva Switzerland. IFPMA is an organization comprising global pharmaceutical and vaccine companies and 55 national associations across the world with a focus on scientific, regulatory, ethical and market issues. While at IFPMA, Dr. Bale was also a founder and President of Pharmaceutical Security Institute (PSI), the pharmaceutical and vaccine industry's anti-counterfeiting organization comprising 25 global companies from the U.S., Europe and Japan. Dr. Bale continues his work as an international consultant based in Washington, DC and serves on the Advisory Board of RegLink Associates, a recently formed company providing regular updates on changes in regulations concerning biopharmaceuticals and medical devices.

Dr. Bale's professional interests lie in the areas of: controlling counterfeit medicines from a public health perspective; potential roles for private sector and NGOs in improving global public health, particularly relating to pharmaceutical technology in emerging and developing countries; public-private partnerships for increasing medicine quality, access, and development; improvement in the supply of quality medicines in developing countries; and the impact of intellectual property issues on medicines access and drug development in developing countries. His involvement at the highest levels internationally is a reflection of the experience and understanding he brought to deliberations. Accomplishments include: Steering Committee, International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and Global Cooperation Group under the ICH Steering Committee; Steering Committee, World Health Organization (WHO) International Medical Products Anti-Counterfeiting Task Force (IMPACT) and Chair of IMPACT's Technology Subgroup; leading roles in the creation of the Medicines for Malaria Venture (a pioneer public-private malarial drug partnership) and in the creation of the Global Alliance for Vaccines and Immunization (GAVI) – a public-private partnership to expand vaccine access in developing countries; member of the Private Sector Delegation to the Board of the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Dr. Bale also served as Assistant US Trade Representative for Intellectual Property, Investment Finance and Policy, Executive Office of the President of the United States and was a White House designated representative to the Post-Camp-David Middle East Peace Negotiations for several months in 1980. He also received the Presidential Distinguished Service Award – the highest lifetime service award earned by US career civil service professionals in 1986, and received the Founders Award from the Pharmaceutical Security Institute.

**Statement of Interest:** Following a rewarding government career, my work over the past two decades focused on global biopharmaceutical and vaccines issues, with emphasis on access, quality and innovation – with focus not only on developed countries, but also on emerging and developing countries. Given the limited resources challenging the mission of *all* organizations, it is critical for USP's mission success to leverage its organizational expertise to partner with other interested stakeholders. I believe that I bring solid leadership experience – e.g., contributing to the establishment of MMV, GAVI, the Global Fund and WHO/IMPACT – in the identification of shared values and objectives necessary to bring stakeholders together. I am pleased to be nominated as a USP Trustee-at-large, and I would support the USP leadership in identifying and developing new USP collaborative projects. USP's successful experience with quality issues augurs well for it to be a key partner in improving global health care in years ahead.

**AT LARGE TRUSTEE**  
**ENRIQUETA BOND, PH.D.**



Dr. Bond is President Emerita Burroughs Wellcome Fund and is senior consultant to philanthropic and non-profit organizations on program development, governance, leadership, organizational structure and function. Program interests include medical research, health and science policy and K-12 science and math education. Her background is in molecular biology and genetics, but her interests in science and health policy were honed by 20 years at the Institute of Medicine/ National Academy of Sciences where she held positions as program officer, division director and executive officer.

Subsequently she was recruited to head the Burroughs Wellcome Fund as it transitioned to an independent foundation from a corporate foundation. As President she worked with the Board to define a program of awards, hire the staff, build the building and the institution. At the Institute of Medicine, Dr. Bond oversaw the work of the Food and Nutrition Board which did work on numerous reports of interest to USP such as the *Food Chemical Codex* as well as work that reviewed the work of the FDA. She has served on the CDC Board of Advisors to the National Center for Infectious Diseases, the Council of the National Institute of Child Health and Human Development, The NIH Council of Councils, The National Library Board of Regents, the Institute of Medicine Council, the Board of the North Carolina Biotechnology Center, the Board of the Hamner Institute for Health Sciences, Board of the Health Effects Institute, the Merck Vaccine Advisory Board and served a number of similar organizations that work on issues important to human health.

A selection of Dr. Bond's awards and recognition are below:

- Wellesley College Alumnae Achievement Award, the highest honor given to alumnae for excellence and distinction in their fields of endeavor, 2009
- Awarded the *Order of the Long Leaf Pine*, the highest civilian honor that can be awarded in the state of North Carolina by the Governor of North Carolina, 2008
- James B. Hunt, Jr. Institute for Educational Leadership and Policy Award for Outstanding Leadership on behalf of science and math education in North Carolina, December, 2007
- Selected as an Inductee into the YWCA Academy of Women in the Science and Technology Category, 2006
- Elected to the rank of AAAS Fellow for distinguished contributions to the study and analysis of policy for the advancement of the health sciences and to policies related to improving the public health, American Association for the Advancement of Science, 2004
- Awarded Institute of Medicine Walsh McDermott Medal in recognition of distinguished service to the Institute and to the National Academies over an extended period of time, 2002
- Elected to the Institute of Medicine, 1997
- National Academy of Sciences Professional Staff Award, 1985
- Selected for Leadership Seminar on Women in Academic Medicine, sponsored by the American Medical Women's Association, May 1977

**Statement of Interest:** My entire career has been spent advancing the mission of non-profit organizations working to improve the health of the public. I have proven leadership skills and am very familiar how to build and nurture strong institutions. My style is collaborative and to work for consensus. I have long admired the work of USP and believe there is a critical need for an organization that provides independent neutral space where government, industry, and academia can meet to develop standards for medicines, foods and health products. My experience at the Institute of Medicine, the Burroughs Wellcome Fund, and service on numerous Boards has provided me with an understanding of the role of science in informing good policy and the need to protect the integrity of process for setting standards. I am honored to be considered as a candidate for trustee at large.





**AT-LARGE TRUSTEE**  
**JUDITH A. OULTON, R.N., M.ED.**

Judith A. Oulton has served on the USP Board of Trustees as an At-Large member since 2007. She is currently an independent health policy consultant and a visiting professor in the University of Toronto's nursing faculty. She serves on the Leadership Advisory Board to the President of Royal Roads University in Canada, as a member of the International Committee of the Princess Sringarinda Award in Thailand, and as a member of the WHO Strategic and Technical Advisory Committee for HIV/AIDS (STA-HIV), Geneva.

During 2008-09 Oulton held the University of California's Presidential Chair and completed her term as an inaugural member of the board of the Global Health Workforce Alliance, Geneva. She is the former Chief Executive Officer of the Geneva-based International Council of Nurses (ICN), a federation of 133 national nurses associations representing the more than 13 million nurses worldwide. Prior to joining ICN in 1996, Oulton served for seven years as the Executive Director of the Canadian Nurses Association and the Canadian Nurses Protective Society. During her tenure as CEO of the International Council of Nurses, Oulton oversaw the expansion of ICN membership, the development of new models of governance, the implementation of innovative programs for health and nursing services in developing countries and the initiation of new partnerships and strategic alliances. She also spearheaded the creation of the World Health Professions Alliance (WHPA), the global alliance of the nursing, medicine, and pharmacy professions for which ICN acts as secretariat. Her career has included experience in government as Director of Strategic Planning and as Senior Nursing Consultant with major responsibility in hospital organization and budgetary audits; in education as a member of the Nursing Faculty, University of New Brunswick; and in nursing administration and service in a variety of clinical areas. She also was Chair of the Health Action Lobby (HEAL), a coalition of more than twenty Canadian health and consumer organizations.

Oulton's particular areas of expertise include human resources, patient safety, governance, and strategic planning. She holds a Bachelor of Nursing Science and a Master in Education, as well as Honorary Doctorates of Science from McMaster University, Université de Moncton, and the University of New Brunswick. She is a holder of the Queen's Jubilee Medal and in 2008 received the Jeanne Mance Award, the highest honor in Canadian nursing. She has broad experience as a speaker internationally and is the author of numerous articles and book chapters.

**Statement of Interest:** USP represents four areas of keen interest to me, each reflective of my health care experience: patient safety, regulation, good governance and international involvement in health. As the former head of both national and international nursing standard setting organizations, I understand the role and immense responsibility USP shoulders nationally and internationally. Witnessing the lack of knowledge, standards, and regulation in many countries and the impact of substandard and counterfeit medicines makes me increasingly appreciative of USP's vision, mission and activities. Additionally, I believe the nursing perspective will support and enhance USP's growing work serving the health needs of developing countries. During my time on the Board I have been impressed by the accomplishments of the organization and excited by its potential. I believe my background in strategic planning and my experience as a CEO, board member and governance consultant are important attributes at this time in USP's progress.

**AT-LARGE TRUSTEE**  
**FRANK J. SASINOWSKI, B.S., M.P.H., M.S., J.D.**

Mr. Sasinowski is Director at Hyman, Phelps & McNamara, P.C., a law firm specializing in food and drug law with the world's largest concentration of full-time food and drug attorneys. He is interested in all aspects of pharmaceutical/medicine development including issues related to drug substance and final dosage form development and manufacturing.



Mr. Sasinowski serves as Vice Chair of the National Organization for Rare Disorders (NORD), which represents 30 million Americans with rare disorders and was the chief force behind the creation of the U.S. orphan drug law and then has helped spur orphan drug development across the globe. He is also Vice Chair of the Catholic Medical Mission Board (CMMB), which has been in Haiti for 100 years and was the only U.S.-based NGO doing AIDS work in Africa before PEPFAR and last year donated more than \$250 million worth of medicine to those most in need across the world without regard to religion and without any hint of proselytizing for fear of discouraging even one person in need from seeking help. Prior to Sarbanes-Oxley, Mr. Sasinowski also served on Boards of two biotech firms.

Mr. Sasinowski received the 2000 NORD Humanitarian Award for “continuing commitment to orphan drugs and the orphan disease community.” He is also the recipient of multiple Awards of Merit from FDA (1983-1987) where he provided leadership in several domains:

- Led analysis of original Orphan Drug Act that resulted in the 1984 and 1985 amendments which transformed law and made it viable which enabled it to become highly successful;
- Was one of 6 selected by FDA Commissioner to lead FDA’s implementation of Title I of 1984 Hatch-Waxman law;
- Led FDA’s implementation of patent extension provisions of that 1984 law; and
- Chaired Interagency Committee on Drug Control (ICDC), panel with monthly meetings of DEA/NIDA/FDA officials on issues related to controlled substances.

**Statement of Interest:** My over a quarter of a century of experience, both within FDA and counseling Pharma/PMA corporations, biotech companies and generic firms, has given me an acute appreciation for the invaluable contribution of the USP and an understanding of why Congress recognized USP with singular prominence in the original 1906 Pure Food and Drug Act. The standard setting role of USP is timeless in that it looms as key today as it did more than a century ago in 1906. If elected to serve, I would hope to apply my experience to the issues before the USP. The reach of the USP into health issues in the U.S. and around the world is pivotal and I would welcome the opportunity to lend a “hand” in those efforts.



**AT-LARGE TRUSTEE**  
**THOMAS R. TEMPLE, R.PH., M.S.**

Thomas R. Temple is the Executive Vice President and CEO of the Iowa Pharmacy Association (IPA), a position he has held since 1980. Mr. Temple received a B.S. degree in Biology from Northern Illinois University (1971), a B.S. degree in Pharmacy from the University of Illinois (1975) and a M.S. degree in Pharmacy Administration from the University of Iowa (1977). In addition to serving as executive officer of IPA, Mr. Temple also serves as CEO of the Iowa Pharmacy Foundation (IPF) and the Collaborative Education Institute (CEI) – two subsidiary and related corporations of the Iowa Pharmacy Association.

Mr. Temple has served as the Iowa Pharmacy Association's Delegate to the USP Convention since the 1995-2000 cycle and was a candidate for Treasurer in 2000.

Mr. Temple is currently the Chair of the USP Convention Membership Committee and serves as Membership Committee liaison to the Council of the Convention.

Mr. Temple is a member of several professional organizations including the IPA, the American Pharmacists Association (APhA), the National Alliance of State Pharmacy Associations (NASPA), and the American Society of Association Executives (ASAE). A past president of NASPA, he has served as a Board member for the Alliance for Patient Medication Safety, Pharmacy Marketing Group, and the Iowa Initiative to Reduce Unintended Pregnancies. His past experience includes membership on numerous professional committees including the Medic Alert National Task Force, ACPE's CE Advisory Council, ACPE's Doctoral Fellowship Committee, the State Advisory Panel to the National Pharmacy Technician Certification Board and Advisory Committees for Drake University, the University of Iowa, and the University of Illinois Colleges of Pharmacy. He has also served as a member of Pharmacy Advisory Boards for Upjohn, Glaxo Wellcome, Merck, Hoechst Marion Rousell, and PCS.

Mr. Temple's leadership has been recognized through several awards including APhA's Gloria Neimeyer-Francke Leadership Mentor Award, the Medic Alert Outstanding Service Award, the University of Illinois' College of Pharmacy Alumnus of the Year Award, the University of Iowa College of Pharmacy Alumnus of the Year Award and the University of Iowa Distinguished Alumni Award for Service.

**Statement of Interest:** Over the past decade it has been a privilege to serve USP in a variety of volunteer positions – Delegate, Candidate for Treasurer, Chair of the Membership Committee and Membership Committee liaison to the Council of Convention. These avenues of professional involvement have afforded me a unique opportunity to witness the broadened scope of work USP has undertaken on a global basis and the unprecedented growth and credibility it has as an organization whose mission is to improve the health of people through public standards that ensure quality of both medicines and foods. It would be an honor to serve as a USP Trustee working in a collaborative and interdisciplinary effort to further that critical mission, and to maintain USP's unique legacy as an independent and self-supporting, practitioner-based organization dedicated to promoting public health.

**AT-LARGE TRUSTEE**  
**GAIL WILENSKY, B.A., M.A., PH.D.**

Gail Wilensky is an economist and a senior fellow at project HOPE, an international health foundation. She develops and analyzes policies relating to health care and the economy; serves as a formal and informal advisor to government and the private sector, and writes and speaks about policies and politics of health care reform. Dr. Wilensky has served in the past as Visiting Assistant Professor and Associate Research Scientist at the University of Michigan, with joint research and teaching appointment in the Department of Economics and the Institute of Public Policy Studies. Her teaching responsibilities included public finance and public sector decision-making. Dr. Wilensky serves as a trustee of the Combined Benefits Fund of the United Mine Workers of America and the National Opinion Research Center, is on the Board of Regents of the Uniformed Services University of the Health sciences (USUHS) and the Visiting Committee of the Harvard Medical and Dental Schools. She recently served as president of the Defense Health Board, a Federal advisory to the Secretary of Defense, was a commissioner on the World Health Organization's Commission on the Social Determinants of Health and co-chaired the Department of Defense Task Force on the Future of Military Health Care.



Dr. Wilensky testifies frequently before Congressional committees, serves as an advisor to members of Congress and other elected officials, speaks nationally and internationally before professional, business and consumer groups. She has earned honorary degrees from The University of the Sciences in Philadelphia, Rush University and Hahnemann University. She was a Marshall J. Seidman Lecturer at Harvard Medical School, John D. Thompson Distinguished Visiting Fellow for Yale's Health Management Program, and TeKolste Scholar for Indiana Hospital and Health Association. She is a Member of Institute of Medicine, National Academy of Sciences and was named Flinn Foundation Distinguished Scholar in Health Policy and Management in 1989. She has been named in *Who's Who in America* and *Who's Who of American Women* continually since 1989 and was named as one of the most 100 powerful people in healthcare (2003, 2004) and as one of 25 top women in healthcare (2005) by *Modern Healthcare*.

Dr. Wilensky has won the following awards:

- Senator John Warner Champion for Military Health Award, Military Health System Conf. (2008)
- Darrel J. Mase Distinguished Leadership Award, University of Florida (2000)
- The Latiolais Honor Medal, The American Managed Care Pharmacy Association (1996)
- Dean Conley Award, American College of Healthcare Executives (1989)
- Alumna in Residence Award, University of Michigan (1989)

**Statement of Interest:** USP, with its focus on national product safety, healthcare delivery and patient safety, is positioned to play an increasingly important role in helping the nation and the nations of the world learn to ensure the availability of quality standards and information on the proper use of medicines and other therapeutics. I would be pleased to help them in this process as a member of their Board of Trustees.



CONVENTION

2010

## PART IV

### APPENDIX

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

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**APPENDIX. EXCERPTS FROM THE USP CONSTITUTION AND BYLAWS  
PERTAINING TO THE NOMINATING COMMITTEE  
FOR OFFICERS AND TRUSTEES**

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**BYLAWS**

**Chapter IX—The Nominating Committee for Officers and Trustees**

***Section 1—Appointment of Committee Members***

The Nominating Committee for Officers and Trustees, hereinafter referred to in this chapter as the Committee, shall consist of five members of the Pharmacopeial Convention, one of whom shall be designated as Chairperson, appointed by the President with the advice and consent of the Board of Trustees, not later than six months before the stated meeting. Two of the members appointed shall be members of the Board of Trustees.

***Section 2***

The Committee shall nominate from the membership of the Pharmacopeial Convention or the Council of Experts, two members for the office of President, and two members for the office of Treasurer.

***Section 3***

The Committee shall nominate from the membership of the Pharmacopeial Convention or the Council of Experts sixteen members for the elected office of Trustee, divided into four classes: four shall represent pharmaceutical sciences, four shall represent medical sciences, six shall be without restriction concerning their affiliations, and two shall represent the public. Taking into account the nominees' backgrounds, the Committee may subdivide the ballot within each class, so as to present two nominees for each elected position within the sub-classification.

***Section 4***

The report of the Committee shall be submitted to the Secretary of the Pharmacopeial Convention not later than sixty days before the stated meeting; not later than forty-five days before the stated meeting, the Secretary shall notify the nominees of their selection by the Committee and the date of the stated meeting.

***Section 5***

The Committee shall present its report to the Convention, at which time additional nominations of Convention or Council of Experts members may be made from the floor for Officers and the Board of Trustees, which shall be seconded by at least ten members of the Pharmacopeial Convention and submitted in writing at once to the Secretary. A nomination for Trustee shall indicate in which of the four classes the nomination is being made or, if the ballot has been subdivided, which sub-classification.