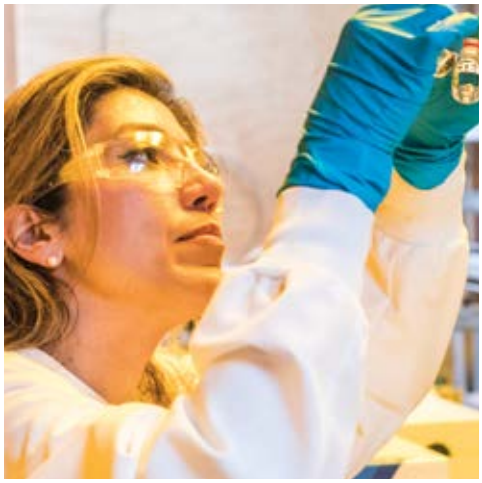


Report to the Board of Trustees on

Council of Experts Activities

2019 Fiscal Year Report

2019

usp.org

Report to the Board of Trustees on Council of Experts Activities

Letter From the Chair

On behalf of the Council of Experts (CoE) and USP staff, I am pleased to present the fourth annual report of the 2015–2020 cycle on the activities and achievements of the CoE, its Expert Committees (ECs), and its Expert Panels (EPs) for fiscal year (FY) 2019.

We have made great progress creating proactive and continuous improvement at USP that will extend into FY 2020 to USP's 2020 Convention, the 200th anniversary of the founding of USP, and beyond.

I want to highlight six of the many notable accomplishments in FY19.
1. As part of USP's 2025 Strategy, we created a new standards ambition. A key focus is for USP to remain a definitive source of medicine quality standards as we aim to adopt a more flexible, agile, and iterative approach to their development and delivery. This new approach will help USP focus on developing solutions to problems, thereby providing the most value to public health and to our stakeholders. USP's approach will make it easier for stakeholders to adopt and use our standards and will also enable USP to remain up to date by addressing new and emerging therapeutic classes, including biologics and biosimilars.

2. The Biologics program developed new approaches that focus on assays and technologies as key factors in evaluating opportunities. With this refined strategy, the Biologics program expanded its portfolio of documentary and Reference Standards. The program is exploring new offerings that support capability building, increased scientific connectivity, and enhanced programmatic relevance, as well as becoming an influencer in the biopharmaceutical space.

3. The Compounding EC published revisions to *USP* General Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations* to reflect advancements in compounding science and practice. In addition, the Chemical Medicines Monographs 4 EC developed the new *USP* General Chapter <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging* in response to stakeholder feedback on addressing the unique characteristics of radiopharmaceuticals. These chapters, along with *USP* General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings,* provide a comprehensive set of standards for all healthcare workers to help ensure preparation of quality compounded formulations and safe handling of hazardous drugs throughout the healthcare system.

4. USP created the Quality Advisory Group to help develop a comprehensive strategy on the future of general chapters. This coalition of scientific professionals from the pharmaceutical industry and regulatory policy space will 1) advise USP on paradigm shifts that ensure quality medicines, 2) identify potential disruptors, and 3) propose pathways for USP to address these challenges and adapt to these shifts. We envision that this collaboration will lead to discussions and data-driven solutions to ensure that quality products are supported by relevant standards in the years to come.

5. The Foods program identified areas where impactful standards are needed to protect public health and the integrity of the supply chain. This led to work on an identity standard for refined olive oil as well as standards for honey and dietary proteins. All are ingredients with a high risk of adulteration, and all are agricultural products that are subject to substantial variability. The Foods program updated its guidance document on using targeted methods to prevent fraud and will be publishing a summary of it in a scientific journal.

6. Chemical Medicines worked with the US Food and Drug Administration (FDA) to expedite the modernization of opioid monographs. This work supported the FDA Opioids Action

Plan for reducing the impact of opioid abuse on American families and communities. Chemical Medicines collaborated with the FDA to support its Drug Competition Action Plan through the development and revision of monographs for products that lack generic competition. Chemical Medicines also supported efforts to develop new and refine existing compendial processes that may represent approaches to mitigate current complex problems such as drug shortages and quality medicines access issues.

These six accomplishments have been supported with the strengthening relationship we have with the FDA through increased collaborations, enhanced engagement, and diversified communication channels with the agency. Our successes in FY19 were made possible by the numerous hours—estimated at 125,500—that were generously contributed by our Expert Volunteers and augmented by our dedicated staff. Thank you for your commitment to USP's mission.

In February, USP's Volunteer Awards and Recognition Program acknowledged the remarkable contributions of USP volunteer bodies and individuals who have worked to improve global health through public standards and related programs. The CoE also launched the new Thomas S. Foster Award, a volunteer-driven process that recognizes the efforts of an individual Expert Volunteer in a USP EC, Subcommittee, Joint Subcommittee, Joint Standards-Setting Subcommittee, or EP. I personally extend my heartfelt thanks and congratulations to all of the deserving award recipients as well as all of the outstanding nominees. I encourage everyone to visit **usp.org/get-involved/volunteer** to learn more about how volunteers contribute to USP's nearly 200-year-old mission, and to click on **callforcandidates.usp.org** to find out how you can start the application process to become a member of our ECs or EPs.

I warmly invite you to read the following pages, which tell the story of how our collaborative activities and accomplishments benefit consumers, patients, and other stakeholders globally by helping to improve and protect public health around the world.

Jaap Venema, Ph.D.
USP Chief Science Officer & Chair,
USP Council of Experts

Our successes in FY19 were made possible by the numerous hours—estimated at 125,500—that were generously contributed by our Expert Volunteers and augmented by our dedicated staff. Thank you for your commitment to USP's mission.

Fostering Collaboration

FY19 at a Glance

CoE Overview

The Council of Experts (CoE), consisting of the 25 Expert Committee (EC) chairs, is one of USP's three governing bodies. Its members direct the scientific standards-setting initiatives for the organization and ensure that these efforts align with USP's Resolutions, policies, and strategies. The CoE oversees the activities of more than 890 global scientific experts who serve on ECs, Expert Panels (EPs), and Joint Standards-Setting Subcommittees (JS3s). JS3s were introduced at the onset of the 2015–2020 cycle to facilitate communication and collaboration on topics that affect multiple standards-setting areas, especially USP Reference Materials.

USP Governing Bodies and Related Groups

Board of Trustees (BoT)	USP Convention	Council of Experts (CoE)
13 members elected by USP Convention and USP CEO, responsible for:	***458 organizations invited by Council of the Convention and BoT, responsible for:***	***25 chairs of USP Expert Committees (ECs) elected by USP Convention, plus the USP Chief Science Officer who serves as CoE Chair, responsible for:***
▸ USP's policies ▸ USP's finances ▸ USP's strategic direction	▸ Resolutions that guide USP policies and initiatives ▸ Adoption of *USP Bylaws* ▸ Election of BoT and CoE	▸ USP scientific and standards-setting decisions ▸ Standards-setting work of USP's volunteer scientific expert groups ▸ Adherence to direction set forth by BoT and USP Convention

USP Staff: Support and shepherd the work of all governing bodies and related groups.

Volunteer Groups Under CoE

ECs
Scientific experts who create, revise, review, and approve standards for a specific topic area. EC members are elected by CoE and serve a five-year term.

EPs
Advisory bodies formed to supplement EC expertise on specific topics. Each has a specific charge and is dissolved upon completion of its work. Members may be EC members or serve on multiple EPs.

JS3s
Representatives from ECs who serve on subcommittees formed to address issues that affect multiple standards-setting areas.

890 global scientific experts serve on Expert Committees, Expert Panels, and Joint Standards-Setting Subcommittees.

USP Standards Approved in FY19

Expert Volunteers play a vital role in approving standards, both documentary standards for publication and Reference Standards for release. Expert Volunteers ballot on all regular documentary standard revisions, new Reference Standards (F Lots), and a sampling of Replacement and Continuation (R&C) Lots.

FY19 Balloted and Approved Standards By the Numbers

171 Ballots

- **55** Accelerated Revisions Ballots
- **48** *United States Pharmacopeia–National Formulary* (*USP–NF*) and *Supplements* Ballots
- **47** Reference Standard R&C Ballots
- **11** Nomenclature Ballots
- **4** Biologics and *Food Chemicals Codex* (*FCC*) Reference Standard F Lot Ballots
- **4** Harmonization Ballots
- **2** *FCC* and *Supplements* Ballots

687 Items Balloted

- **372** *USP–NF* Standards
- **101** Nomenclature Items
- **97** Accelerated Revisions
- **62** Reference Standard R&C Lots
- **44** *FCC* Standards
- **6** Biologics and *FCC* Reference Standard F Lots
- **5** Harmonized Standards

482 New or Revised Documentary Standards Approved

- **184** Revised *USP–NF* Standards
- **101** New Nomenclature Standards
- **97** Accelerated Revisions
- **51** New *USP–NF* Standards
- **40** *FCC* Revised Standards
- **5** Revised Harmonized Standards
- **4** New *FCC* Standards

143 Modernized Documentary Standards Approved

- **124** Modernized *USP–NF* Standards
- **18** Modernized *FCC* Standards
- **1** Modernized Harmonized Standard

137 *USP–NF* Standards Omitted

494 Reference Standard R&C Lots Released

96 Reference Standard F Lots Approved

FY19 Key Activities and Accomplishments

USP established 10 science workstreams led by USP staff who will provide recommendations in the following areas: new analytical technologies, physical and digital Reference Standards, new quality paradigms, impurities, scientific connections, knowledge management, digital health, and dosage-form performance testing.

The CoE met six times during FY19, focusing on the following high-level priorities:

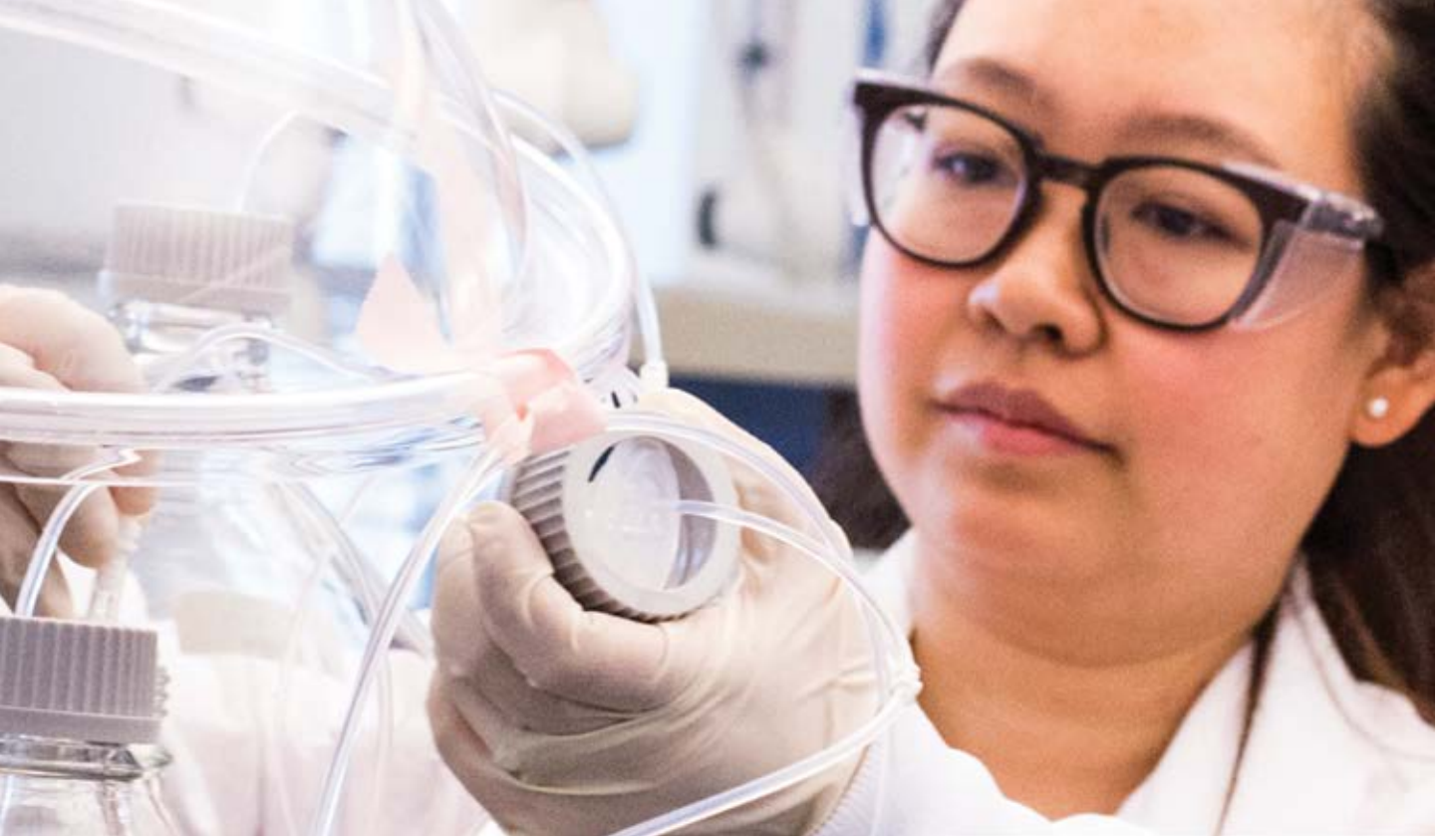
Visionary Science Strategy: USP's long-term science strategy includes the following five top-level visions for the future of science at USP:

- Become a leading provider of value-added data and information. This will support decision-making throughout product and service lifecycles to help ensure quality and patient safety.
- Facilitate standardization of key new scientific paradigms throughout product lifecycles. This will advance how USP ensures the quality and performance of current and future healthcare and foods.
- Lead the exploration, development, and adoption of key analytical technologies. This approach holds promise for improving quality and reducing costs.
- Proactively build a scientific community around USP. This will help USP incubate, shape, and validate its work.
- Harness the latest data/information technology. This will improve how USP works, delivers solutions, and sets priorities.

To advance this work, USP established 10 science workstreams led by USP staff who will provide recommendations in the following areas: new analytical technologies, physical and digital Reference Standards, new quality paradigms, impurities, scientific connections, knowledge management, digital health, and dosage-form performance testing.

Impactful People: The Global People Strategy, a key enabling component of USP's 2025 Strategy, is our roadmap to develop, connect, and inspire USP's Expert Volunteers and staff to achieve our mission and increase our impact. This strategy includes the following goals: 1) develop agile leaders equipped to effectively lead complex global change; 2) build strategic capability to deliver on the 2025 Strategy; 3) enable USP to collaborate in a complex, globally matrixed environment; 4) foster a diverse and inclusive multi-generational culture by creating a valued volunteer and staff experience; and 5) implement people analytics and digital tools for decisions, strategies, and technologies that foster efficiency and collaboration.

Reimagining USP's Volunteer Model: USP's volunteer model is evolving. The goal is to explore new ways to attract, engage, and retain leading experts and harness their spirit of volunteerism to help advance USP's science and public health mission. USP will pilot test a flexible volunteer model for some ECs. This will include



experimenting with a more flexible time commitment and allowing volunteers to engage in work that most interests them and best leverages their unique skill sets. USP will collect feedback on the pilot program throughout the 2020–2025 cycle in a continuing effort to engage and support our volunteers while finding new ways to maximize their impact.

Scientific Expert Fellowship: This program is designed to promote a more diverse and inclusive Expert Volunteer body. USP will partner with scientific organizations to identify candidates for five to six Scientific Expert Fellowship opportunities. The program's objective is to expand recruitment efforts and provide opportunities for scientists from underrepresented populations to learn about USP, share their USP experiences with their organizations, and broaden awareness of USP as a volunteer opportunity.

Thomas S. Foster Award: The CoE launched the new Thomas S. Foster Award, a volunteer-driven process that recognizes the efforts of an individual Expert Volunteer in a USP EC, Subcommittee, Joint Subcommittee (JS), JS3, or EP. The award is in honor of the late Dr. Thomas S. Foster, whose involvement with USP spanned nearly two decades and included myriad contributions.

Patient Access to Affordable Medicines: Chemical Medicines worked with the FDA to support its Drug Competition Action Plan with the goal of increasing access to quality generic medicines. USP analyzed the FDA's list of off-patent products for which generic alternatives are not available on the market and engaged the FDA—including senior leadership—as well as manufacturers, patient groups, and other stakeholders to identify potential compendial solutions to enable the development of quality generics for these priority medicines.

New Excipient Monograph Titles: The Excipient Nomenclature JS is critical to excipient naming, the excipients up-to-date initiative, and development of the framework for the *Nomenclature Guidelines for Excipients*. The JS is developing a *Stimuli* article to address how to develop official nomenclature for polymeric excipients often used in specialized drug delivery systems such as biologic and parenteral drug products.

Biologics

The Biologics program maintains and modernizes standards for peptides, proteins, blood products, vaccines, antibiotics, carbohydrates, tissues, and raw materials for manufacturing. In addition, during FY19, the Biologics program continued to develop new standards that support cutting-edge technologies, such as cell and gene therapies. By doing so, the Biologics program has worked to fulfill Resolution VI, which calls for USP to promote alignment with stakeholders to develop quality standards for biological medicines, ensuring that innovation and availability are facilitated and complemented.

FY19 Highlights: Biologics

- 4 New General Chapters
- 9 Revised General Chapters
- 1 New Monograph
- 20 Revised Monographs
- 24 Reference Standards Released

"The USP standard/monograph benefits patients because it sets the standard for product quality, and it also teaches manufacturers how to demonstrate that their product meets those standards."

Wes Workman, Ph.D.
Chair, General Chapters –Biological Analysis EC

"The BIO1 EC'S most important achievement was the publication of *USP* General Chapter <1503> *Quality Attributes of Synthetic Peptide Drug Substances* in *Pharmacopeial Forum* (*PF*) 45(3) [May–June 2019]. This chapter provides the framework for defining the quality standard for peptide drug substances and will drive consistency in future monograph modernization efforts and the development of standards for new peptide therapeutics. It will serve as an indispensable resource for standardization of quality for this important therapeutic class, ultimately benefiting patients, manufacturers, and regulators."

Michael R. De Felippis, Ph.D.
Chair, Biologics Monographs 1–Peptides and Insulins (BIO1) EC

Safeguarding the quality of medication is fundamental to protecting public health, especially as ingredients and products come from all over the world.

FY19 Key Activities and Accomplishments

New Biologics Strategy: The Biologics program's new strategy focuses on developing standards that address key analytical challenges and support biologics testing throughout the product lifecycle. Two new teams were created to facilitate this work: 1) Pipeline Development, which will work with stakeholders to identify opportunities for new standards, collaborate with internal and external laboratories to demonstrate proof of concept, and transfer the results to the compendial team for standards production; and 2) Education and Training, which will create a broader awareness of standards in development by placing a greater emphasis on offering educational webinars, training, and workshops to stakeholders.

Performance Standards: Outreach efforts have continued to successfully identify the most pressing manufacturer needs, such as standards that are widely applicable across a biologics product class. To meet this challenge, the Biologics program has focused on creating performance standards for monoclonal antibodies and host cell proteins that have broad applications across multiple production sites. Several proof-of-concept studies are underway to address critical bottlenecks in manufacturing. In addition, USP scientists continually consult with the ECs to confirm the relevance of these initiatives and to manage the paths to market.

Host Cell DNA Standards and Methods: The Biologics program published *USP* General Chapter <509> *Residual DNA Testing* to address

longstanding industry needs for standardized methods to quantify host cell DNA impurities that occur during manufacturing. The chapter provides several validated methods, including a sample extraction procedure in combination with a quantitative polymerase chain reaction detection method. Two Reference Standards were also approved for compendial use with <509>, the *Escherichia coli* and Chinese Hamster Ovary Genomic DNA Reference Standards.

Webinars, Roundtables, and a Stakeholder Forum: The Biologics program presented a series of webinars with guest speakers who presented on hot topics important to biologics stakeholders. The program also held roundtables on 1) performance standards development for chromatographic column qualifications, 2) visible particles, 3) mRNA standardization, 4) gene therapy standardization, and 5) quantitation of trace metals in cell culture media. In many cases, participants reached consensus on the most beneficial standards and methods, and the Biologics program has begun proof-of-concept studies for evaluating the feasibility of those with the most significant potential. The Biologics Pipeline Development team will continue to collaborate with stakeholders to advance standards with the greatest impact into the next cycle. Finally, the program created a new Biologics Stakeholder Forum and planning committee.

Workshop: USP's 5th Workshop on Therapeutic Peptides brought together quality analysts, scientists, managers, and regulatory affairs specialists to discuss the regulatory expectations for peptide biologic products and to provide feedback about proposed changes to monographs and chapters.

"Of the work our EC completed this past year, I believe the BIO3 EC's revision of *USP* General Chapter <1043> *Ancillary Materials for Cell, Gene, and Tissue-Engineering Products* will likely have the greatest impact on industry as it was significantly overhauled and made current with input from industry and FDA. Ancillary materials are widely used in the production of these products, and this chapter provides up-to-date guidance on them."

Edward K. Chess, Ph.D.
Chair, Biologics Monographs 3–Complex Biologics (BIO3) EC

USP is committed to ensuring that our approach evolves with the science of biologics and the needs of stakeholders, including patients, practitioners, industry, and regulators. We are developing standards that are broadly applicable across biological products and delivering solutions to address the quality of raw materials as well as the development of performance standards that support analytical testing throughout the product lifecycle.

Chemical Medicines

FY19 Highlights: Chemical Medicines

42 New Monographs

170 Modernizations

156 Omissions

Chemical Medicines is responsible for developing and revising monographs for drug substances and drug products. As such, it aspires to be the leader in medicine supply chain quality by providing high-quality, up-to-date standards and unique services across the product development lifecycle to small molecule generic manufacturers and regulatory agencies worldwide. Chemical Medicines is exploring new areas to increase its public health impact and growth, specifically in over-the-counter (OTC) medicines used by millions of people around the world. Chemical Medicines continues to increase and broaden its communication and collaboration with the FDA and its government liaisons on monograph development and validation, in alignment with Resolution I, through systems such as the Cooperative Research and Development Agreement (CRADA) and the FDA OTC Drug Products Working Group.

"In response to the opioids epidemic, Chemical Medicines prioritized the modernization of opioid monographs to ensure that public standards for this important class of drugs contain state-of-the-art procedures to provide assurance of quality."

Edwin L. Gump, Ph.D.
Senior Director, Science–Chemical Medicines

FY19 Key Activities and Accomplishments

***USP* General Chapter <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*:** *USP* General Chapter <825> was published in *PF* 44(5) [Sept.–Oct. 2018]. This chapter describes the controls, training, qualifications, and procedural standards for processing sterile radiopharmaceuticals. The standards describe strategies for maintaining patient safety while ensuring the safety of the individuals who perform these activities. Chemical Medicines evaluated all comments from interested parties and synchronized the publication of <825> with related *USP* General Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations*.

Opioids Action Plan: Chemical Medicines worked with the FDA to expedite the modernization of opioid monographs to support the FDA Opioids Action Plan. Chemical Medicines has also worked with the FDA on innovations in opioid standards, such as exploring the compendial role of an opioid screening test to safeguard the US drug supply chain.

OTC Standards: Chemical Medicines developed several OTC monographs and collaborated with the FDA and the Consumer Healthcare Products Association on the development of innovative compendial pathways for OTC monographs that are flexible for industry and also meet the FDA's regulatory requirements. Toward those ends, a general principles document and a USP OTC drug product monograph mock-up were developed for stakeholder review.

Chemical Medicines is exploring new areas to increase its public health impact and growth, specifically in the area of OTC medicines used by millions of people around the world.

Patient Access to Affordable Medicines: Chemical Medicines worked with the FDA to support its Drug Competition Action Plan. USP analyzed the FDA's list of off-patent products for which generic alternatives are not available on the market. USP engaged the FDA—including senior leadership—as well as manufacturers, patient groups, and other stakeholders to identify potential compendial solutions that will enable the development of quality generics for these priority medicines.

Collaboration with the FDA: USP and the FDA began seven new projects under the CRADA program. Chemical Medicines collaborated with the FDA and instrument and column manufacturers to modernize and develop new USP Reference Standards.

Pending Monograph Process (PMP): The PMP, a collaborative effort between USP and the FDA, provides a transparent and efficient pathway to align the development of monographs with FDA approval of the associated applications. Chemical Medicines worked with the FDA on establishing mutually beneficial best practices for this critical program. The FDA's long-awaited draft guidance for industry, titled *Harmonizing Compendial Standards With Drug Application Approval Using the USP Pending Monograph Process*, was issued in July 2019.

The Critical Resources–Information Sharing Priorities (CRISP) Initiative: Collaboration and communication are key to the development of standards, especially when exchange of critical confidential information is needed. Through the CRISP Initiative, Chemical Medicines has worked with the FDA and industry on various efforts to strengthen collaborations and develop potential pathways for the exchange of such critical information. This work could significantly enhance the efficiency of the standards-development process for all.

Compendial Communications: Chemical Medicines worked with the FDA to enhance our compendial communication process. Both the FDA and USP committed to establishing best practices, and initial work has led to demonstrable progress. For example, to decrease the rate-limiting *PF* discussions, USP has developed an FDA-supported, streamlined, centralized process for sharing essential monograph revision information significantly earlier in the development process.

Dietary Supplements and Herbal Medicines

FY19 Highlights: Dietary Supplements and Herbal Medicines

- 23 New Dietary Supplement Monographs
- 3 New *Herbal Medicines Compendium* Monographs
- 15 Modernized Monographs
- 22 Revised Monographs

"Quality standards for botanicals carry immense public health impact due to the wide use of dietary supplements by global populations. Botanicals are complex in nature and subject to adulteration due to their global supply chain. To increase the reach of USP quality standards to global stakeholders, USP provided science-based inputs to voluntary consensus standards-development organizations and encouraged adoption of USP Standards through their stakeholders to protect public health."

Nandakumara D. Sarma, Ph.D.,
Director, Dietary Supplement Standards

"Probiotics are among the most rapidly growing dietary supplement classes. In response, USP's Probiotics EP finalized *USP* General Chapter <64> *Probiotic Tests* and developed new quality standards for four probiotic strains."

Dennis K.J. Gorecki, Ph.D.
Chair, NBDS EC

The Botanical Dietary Supplements and Herbal Medicines (BDSHM) and Non-Botanical Dietary Supplements (NBDS) ECs develop and revise monographs, general chapters, and USP Reference Standards for the *USP–NF, Dietary Supplements Compendium,* and *Herbal Medicines Compendium*. These quality standards help protect and improve the health of many people who purchase OTC dietary supplements and herbal medicines. In addition, the USP Verification Program created specifically for these products gives manufacturers the tools they need to help safeguard the health of consumers. Brands that display the USP Verified Mark signal to the public that what's on their label is what's in the bottle, allowing their vetted product to stand apart from a majority of the competition.

FY19 Key Activities and Accomplishments

***2019 Dietary Supplements Compendium* (DSC) Online:** Launched in June 2019, this new online-only resource provides an intuitive interface to help users navigate to *DSC* monographs, regulatory guidances, and reference tools used around the world for the dietary supplement supply chain. The *2019 DSC* features step-by-step procedures and assays to help manufacturers and ingredient suppliers demonstrate that their raw materials and finished dietary supplement products meet established specifications for identity, strength, quality, purity, packaging, and labeling.

DNA Methods for Botanical and Probiotic Identification: USP is continuing the development of species-specific DNA-based methods for botanical identification of closely related species. General chapter guidelines are under development to support this effort. Orthogonal tests using compendial chromatographic methods are being conducted to study the correlation between the different identification methods. New genomic Reference Standards for probiotic strains are being explored. In addition, a scientific article titled "Improving End-User Trust in the Quality of Commercial Probiotic

Products," authored by members of the Probiotics EP of the NBDS EC, was published in *Frontiers in Microbiology,* a leading peer-reviewed journal.

Cannabis Standards: USP is committed to bringing our public health mission and expertise to this developing area through publications and information-sharing. The Cannabis EP of the BDSHM EC is finalizing the quality parameters for cannabis inflorescence. These specifications define appropriate tests for identification and quantitation of the different chemotypes as well as limits for contaminants such as elemental impurities, pesticide residues, microbial load, and aflatoxins. USP is drafting a manuscript for publication in a peer-reviewed journal to serve as a scientific resource and commentary on the feasibility of setting public quality standards that provide transparent, scientifically validated analytical methods and specifications.

Stakeholder Outreach: Manufacturers, trade associations, service providers, and others who attended the USP Dietary Supplements Stakeholder Forum in May 2019 at USP–US, Rockville, MD, discussed high-impact topics related to the quality of supplements. Topics included hemp standards, pesticide residue limits, food allergen testing, and probiotics. Stakeholders provided feedback on the role of USP public standards in light of FDA initiatives to modernize dietary supplement regulations.

Advocating Use of Public Standards: USP signed a memorandum of understanding with the Food Safety and Standards Authority of India to support the recent recognition of USP Standards in India's health supplement regulations. In accordance with Resolution XI, which relates to increasing its commitment to global public health, USP encouraged the adoption of science-based USP Standards in India, China, Brazil, and South Korea to protect public health. Academic, industry, and regulatory stakeholders were also engaged in the effort.

"Setting quality standards that help reduce risk, members of the BDSHM, NBDS, and Food Ingredients ECs and USP staff are collaborating on innovative, flexible monographs with modern analytical methods to help detect adulteration. These modern methods include quantitative nuclear magnetic resonance for aloe and matrix-assisted laser desorption ionization–time-of-flight mass spectroscopy for cranberry. In addition, the Green Tea Extract Hepatotoxicity EP has partnered with industry and the Drug-Induced Liver Injury Network to prepare a comprehensive peer-reviewed article examining possible causal factors in this serious health risk."

Robin J. Marles, Ph.D.
Chair, BDSHM EC

USP's quality standards help safeguard the health of millions of people who purchase dietary supplements and herbal medicines.

Excipients

USP's Excipient Monographs 1 and 2 (EM1 and EM2) ECs are continually updating excipient monographs by introducing modern analytical techniques that help establish specifications for excipients as well as their components and impurities. The work of the two ECs helps ensure that excipients are fit for purpose and addresses potential threats from the complexities of global supply chains. USP's Up-to-Date, outreach, and harmonization work show that USP is committed to fulfilling Resolutions II and III, which call for up-to-date monographs and globally harmonized standards to benefit all stakeholders.

FY19 Highlights: Excipients

- 5 New Monographs and 15 Monograph Modernizations Approved for Adoption in *USP–NF*
- 3 New Monographs, 21 Monograph Modernizations, and 2 General Chapter Major Revisions Published for Public Review in *PF*
- 12 F Lots
- 48 R&C Lots
- 3 Pharmacopeial Discussion Group (PDG) Stage 4 (Formerly Stage 6) Postings on USP.org
- 3 PDG Stage 2 (Formerly Stage 4) Monographs Published for Public Review in *PF*
- 4 Harmonized PDG Monograph Sign-Offs and 3 Monograph Sign-Off Cover Page Revision Sign-Offs

"Excipients—considered 'inactive' ingredients in medicine—can comprise up to 90% of a medication. Therefore, they are critically important to how well a drug works in the body, as well as how it tastes if it's an oral medication. Excipients can also cause great harm to patients if their quality is poor. By creating standards for excipients, USP's Excipients ECs play key roles in ensuring the quality of the whole medication. Our documentary standards provide the appropriate, validated test procedures to establish the identity, purity, and quality of excipients, while our Reference Standards are authentic specimens that have been approved as suitable for use as comparison standards in *USP* or *NF* tests and assays. At every step, we're protecting the public's health by helping to prevent poor-quality medications from entering the marketplace."

Catherine M. Sheehan, M.S., M.S., DRSc.
Senior Director, Science–Excipients

FY19 Key Activities and Accomplishments

New Excipient Monograph Titles: The Excipient Nomenclature JS is critical to excipient naming, the excipients Up-to-Date initiative, and development of the framework for the *Nomenclature Guidelines for Excipients*. The JS is developing a *Stimuli* article to address how to develop official nomenclature for polymeric excipients often used in specialized drug delivery systems such as biologic and parenteral drug products.

Consequential Standards: Work continued on the development of consequential standards, including standards for 1) impurities; 2) novel excipients; 3) excipient performance; 4) supplier qualification; and 5) high-use excipients such as glycerin, talc, lactose, and polysorbates.

Work Plans: The EM1 and EM2 ECs met face-to-face on August 1–2, 2018, at USP–US, Rockville, where EC members discussed strategies, plans, and recurring topics that helped prioritize their Work Plans for the next five to ten years.

External Engagement: USP staff provided presentations and posters at the Excipient World Conference and Expo in May 2019 in National Harbor, MD. Presentations focused on the value of setting meaningful compendial specifications for excipients and USP's modernization and harmonization work on quality standards for excipients. Earlier in FY19, USP hosted the Impact of Nomenclature on Excipient Quality, Drug Product Development, and Labeling Compliance Workshop at USP–US, Rockville, which addressed procedures and issues surrounding the official nomenclature and labeling of pharmaceutical excipients. USP staff also provided excipients presentations at the 1) Asia Pacific Economic Cooperation User Forum in the Philippines, Thailand, Indonesia, and Malaysia as Center of Excellence hosts; 2) International Pharmaceutical Excipients Council (IPEC) roundtable meeting; 3) ExcipientFest Asia meetings in Beijing, China; 4) International Association for Pharmaceutical Technology-IPEC meeting in Cologne, Germany; and 5) USP Excipients User Forum in Hyderabad and Mumbai, India.

Food Ingredients

The Food Ingredients (FI) EC focuses on developing standards for food ingredients to ensure the identity, quality, and purity of food additives, processing aids, flavors, colors, and other substances used in food production. These standards are published in the *Food Chemicals Codex* (*FCC*), which is used by product developers, ingredient suppliers, food manufacturers, testing laboratories, and regulators in the US and internationally. The FI EC works closely with the Botanical Dietary Supplements and Herbal Medicines and Non-Botanical Dietary Supplements ECs to coordinate the development of standards for substances that are used as both dietary and food ingredients. The FI EC aspires to be the definitive source of up-to-date science and standards for the quality of food ingredients that protect public health and the integrity of the food supply in accordance with Resolution X, which relates to food quality and integrity.

FY19 Highlights: Food Ingredients

1 New Monograph

12 Revised Monographs

6 Modernized Monographs

"We in the FI EC are very proud of our contributions to USP's global health impact through our work on food quality and integrity. Our efforts in combating food fraud through the adoption of identity standards for olive oil and guidance for non-targeted assays to detect fraudulent behavior in the food arena, as well as our efforts to combat protein adulteration via the application of logic combined with analytic expertise, are indicative of our dedication. We are proud of our continuing work as the world's leading source of food quality and integrity specifications."

Jonathan W. DeVries, Ph.D.
Chair, Food Ingredients EC

FY19 Key Activities and Accomplishments

Dietary Proteins: The FI EC's Dietary Proteins EP continued its work on developing, validating, and recommending new specifications and analytical tests for dietary proteins. Whey protein concentrate and whey protein isolate are among the prioritized matrices under study. The anticipated outcome is to support the creation of new and modernized *FCC* monographs, identity standards, general tests and assays, and USP Reference Materials.

Food Adulteration: The FI EC's Food Adulteration (FA) EP held a Food Fraud Roundtable on August 23, 2018, at USP–US, Rockville, that focused on advancing the tools available to companies and organizations for addressing economically motivated adulteration and other food fraud threats. The FA EP is now developing a guidance tool designed to help companies prioritize their efforts in the pre-screening of a large number of ingredients.

Honey EP: The FI EC's Honey EP continued its work on developing a honey standard for the US market that would be globally applicable. The EP will consider different types of honey, such as table honey and industrial honey, as well as honey derived from specific plants and produced in different parts of the world.

Olive Oil Authenticity and Quality (OOAQ): The FI EC approved the OOAQ EP's Identity Standard for Olive Oil, Refined, for publication in the *Third Supplement* to *FCC, Eleventh Edition* on September 1, 2019.

General Chapters

FY19 Highlights: General Chapters

11 New Chapters

17 Major Revisions

6 *Stimuli* Articles

5 Workshops

USP General Chapter <60> became official, providing test methods to detect *Burkholderia cepacia* complex bacteria. Also, the GCM EC published *USP* General Chapter <1071>, which provides rapid sterility test methods for short shelf-life products that require prompt administration. Compounders and manufacturers of radiopharmaceuticals and cell therapies need these methods because they yield results before products are shipped or administered to patients and therefore help protect patient health."

David Hussong, Ph.D.
Chair, General Chapters–Microbiology EC

***USP* General Chapters provide specifications on tests, procedures, and other standards, as well as general guidance for *USP–NF* monographs. Expert Volunteers serve on the General Chapters–Chemical Analysis (GCCA) EC, General Chapters–Dosage Forms (GCDF) EC, General Chapters–Microbiology (GCM) EC, General Chapters–Packaging and Distribution (GCPD) EC, General Chapters–Physical Analysis EC, and General Chapters–Statistics (GCSTAT) EC, and their affiliated EPs and subcommittees. Their work impacts the quality control, packaging, and supply integrity of drugs, as well as method validation and verification.**

FY19 Key Activities and Accomplishments

General Chapters Strategy: A Quality Advisory Group was created as part of the development of a comprehensive strategy for the future of general chapters. This group includes thought leaders from the pharmaceutical industry to advise USP by identifying changes in quality paradigms and potential disruptors in a rapidly changing global pharmaceutical manufacturing and regulatory environment. In addition, this group will propose potential pathways that address these paradigm shifts and thereby maintain the relevance of USP's standards in the years to come.

Pharmaceutical Water: The GCCA EC's Water for Analytical Purposes and Pharmaceutical Purposes EP held a successful roundtable on June 6, 2019, at USP–US, Rockville, to discuss alternative approaches for the establishment of a total organic carbon limit for packaged Sterile Water for Injection. The discussion was engaging and productive, and recent data were used to build a proposal.

Packaging Chapters: The GCPD EC finalized the revision draft and implementation date of the suite of plastic packaging chapters. The EC also published a suite of elastomeric closure general chapters.

New Light-Scattering Chapters: New general chapters were published that complete the entire spectrum of applications of light-scattering methodologies for assessing drug product quality attributes. These standards address many of the product testing requirements introduced in two recent FDA guidances for industry.

Microbiology: *USP* General Chapter <60> *Microbiological Examination of Nonsterile Products—Tests for Burkholderia Cepacia Complex* became official, providing test methods for detecting *Burkholderia cepacia* complex bacteria that can contaminate aqueous products,

overcome preservatives, and cause infections. In addition, *USP* General Chapter <1071> *Rapid Sterility Testing of Short-Life Products: A Risk Based Approach* was published to help safeguard public health by providing rapid sterility test methods for short shelf-life products that require prompt administration.

Statistics: The GCSTAT EC revised and balloted *USP* General Chapter <1010> *Analytical Data—Interpretation and Treatment.* The EC also began revising the USP bioassay suite of general chapters to include additional examples and explanations of bioassay development and analysis. The Content Uniformity for Large Sample Sizes JS published a *Stimuli* article that extends the sampling features of *USP* General Chapter <905> *Uniformity of Dosage Units* to larger sample sizes.

Analytical Procedure Lifecycle: The GCCA EC's new Analytical Procedure Lifecycle EP began finalizing the proposed new *USP* General Chapter <1220> *The Analytical Procedure Lifecycle.* In addition, USP is involved in the revision of International Conference on Harmonisation (ICH) Q2 Analytical Validation Guidance and the creation of a new ICH Q14 Guideline on Analytical Procedure Development.

New Advancements in Product Performance Testing: The GCDF EC's New Advancements in Product Performance Testing EP was formed to provide recommendations for the evaluation and adoption of product performance tests and the development of innovative approaches to novel dosage forms.

Healthcare Quality and Safety

FY19 Highlights: Healthcare Quality and Safety

4 Compounded Preparation Monographs

1 Omission

Expert Volunteers serve on the Healthcare Quality and Safety (HQS) EC, Nomenclature and Labeling (NL) EC, and Compounding (CMP) EC, as well as related EPs and subcommittees. Their work impacts patient-centered approaches to safe and effective medicine use, naming and labeling standards for drug products and ingredients, handling of hazardous drugs, and the quality of compounded preparations. Together, these groups work to fulfill Resolutions VII and VIII, which call for quality standards for compounded medicines and healthcare, respectively.

"In FY19, the USP Nomenclature and Labeling EC created over 100 compendial names for drugs, drug substances, compounded preparations, and dietary supplements. What's in a name? We partner with expert groups across USP, government liaisons, and other stakeholders in efforts to ensure quality and safety. Key accomplishments include development of guidance on the Monograph Naming Policy for salt drug substances; finalization of updates for *USP* General Chapter <7> *Labeling;* pronunciation creation or review for hundreds of drug names in the *USP Dictionary;* and collaborative work in updating nomenclature guidelines for the Dietary Supplements and Herbal Medicines Nomenclature Joint Subcommittee."

Stephanie Y. Crawford, Ph.D., MPH
Chair, Nomenclature and Labeling EC

FY19 Key Activities and Accomplishments

Opioids: The HQS EC's Opioids/Naloxone Subcommittee continued its work on developing labeling, storage, disposal, and counseling standards to help reduce opioid abuse. The Subcommittee, in collaboration with the USP Opioids Team, held an opioids labeling roundtable on March 19, 2019, at USP–US, Washington, DC.

Drug Allergy: The HQS EC's Drug Allergy and Intolerance Classification EP continued its work on mapping drug products for specified classes. The EP also developed a peer-reviewed journal article on improved documentation and interoperability of allergy information in health information technology systems.

Parenteral Nutrition: The HQS EC's Parenteral Nutrition Safety EP continued its work on a draft general chapter on minimum standards for safe use of parenteral nutrition. The EP also proposed a stakeholder engagement plan to inform and meaningfully engage external experts and stakeholders prior to publication of the proposed chapter for public comment.

Our standards for clear prescription labeling help patients take their medicines correctly so they can improve and protect their health.

Compounding: USP published revisions to *USP* General Chapter <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations* on June 1, 2019**.** The CMP EC reviewed more than 7,000 total public comments on these two chapters and engaged stakeholders through roundtables, open microphone sessions, and discussion forums. These revised chapters, along with *USP* General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings,* provide a comprehensive set of standards to help ensure the preparation of quality compounded preparations and the safe handling of hazardous drugs throughout the healthcare system. (In addition, USP published new *USP* General Chapter <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging.*) USP continues to offer live and virtual compounding-related courses and has created a Compounding Certification Program through a strategic partnership with the American Pharmacists Association.

Drug Classification: The HQS EC's USP Drug Classification EP finalized the second version of *USP Drug Classification* (*USP DC 2019*), published on January 31, 2019, on USP.org. More than 600 stakeholders, including drug manufacturers, regulators, health plans/pharmacy benefit managers, academia, and patient advocacy groups, have downloaded *USP DC 2019* since its publication. The HQS EC's goal is to create a comprehensive classification system for use in drug formulary development or drug formulary review in non-acute or outpatient care settings. This tool has the potential to provide guidance on the design and comparison of balanced formularies.

Labeling: The NL EC is revising the *Expiration Date and Beyond-Use Date* section of *USP* General Chapter <7> *Labeling* following stakeholder engagement and feedback. The revision will be published in *PF* 45(6) [Nov.–Dec. 2019] and is anticipated to become official on May 1, 2020. The NL EC is also evaluating modifications to ratio expressions of strength for combination products that contain local anesthetics and epinephrine to determine the impact on healthcare providers.

The quality of medicine and how it is delivered to patients are fundamental to treating illness and maintaining health. We help build the safety net across the drug industry and healthcare system, establishing standards to help ensure that a medicine is of the highest quality from the time it is manufactured until the moment someone takes it. Not only do we provide standards for what goes into a medicine and how it is named and labeled, our standards also help ensure that once the medicine is in the hands of a healthcare team, it is prepared and handled safely.

Our Expert Volunteers

Nagarajan A, EP
Jibril Abdus-Samad, EP
Grant Abernethy, EP, JS3
James Agalloco, EC
Amit Agarwal, EP
David Aguero, EP
Emmanuel Akala, EC
Samuel Akapo, EC
James Akers, EC, EP
Michael Akers, EC, EP
Ilgaz Akseli, EC, EP (2)
Mahmoud Al Omari, EC
Mehrshid Alai, EC
Timothy Albertson, EC
Dale Aldrich, EC, EP (3)
Shaukat Ali, EC, EP (3)
Ahmad Almaya, EP
Gregory Amidon, EP
Jan Amstrup, EP (2)
Gennady Ananchenko, EC
Om Anand, EP
Christopher Anderson, EC, EP
Edwin Anderson, EC, EP
Pascal Anger, CoE, EC (2), EP
Fernando Antunes Lopes, EP, JS3
Vathani Arudchandran, EP
Wilfried Arz, EC, EP, JS3
Dilip Ashtekar, EC
Lisa Ashworth, EC
Yves Aubin, EP
Bianca Avramovitch, EC, JS3
Phil Ayers, EC, EP
John Ayres, EP
Parastoo Azadi, EC, JS3
Steven Baertschi, EP
Danial Baker, EC, EP
Mary Baker, EC, EP
Douglas Ball, EP (2)
Stephen Barat, EP
Amy Barker, EC
Matthew Barlow, EP
David Barnes, EP
Kimber Barnett, EP (2)
Charles Barton, EP
Gus Bassani, EC
JaCinta Batson, EP
Gregory Beck, EC, EP
Gudrun Beckh, EP
Klaus Beckmann, EP
Tim Begley, EP
William Beierschmitt, EP
Robert Bell, EC, EP, JS3
Sandra Benavides, EP
Luca Benetti, EP
Corinne Bensimon, EP
Dan Berdovich, EP
Svetlana Bergelson, EC
James Bergum, EP
Eden Bermingham, EP
Francesco Berti, EP
Joseph Betz, EC, EP (2), JS3
Anthony Bevilacqua, EC, EP (2)
Mahesh Bhalgat, EC
Sneh Bhandari, EP
Ashwinkumar Bhirde, EP
Alberto Biavati, EP
Lynn Blessing, CoE, EC
Richard Blessing, CoE, EC
Lawrence Block, EC (2), EP, JS3
Andrew Bluj, EC
Barbara Blum, EC
Elizabeth Bobo, EP
Judy P. Boehlert, EP
Denise Bohrer, EP (3)
Allan Bokser, EC
Seamus Boland, EC
David Bolliet, EP, JS3
Bettine Boltres, EC, EP
Thierry Bonnevay, EP
Jeri Ann Boose, EP
Dawn Boothe, EC
Matthew Borer, EC, JS3
Jon Borman, EP
Phil Borman, EP
Bruno Boulangerr, EC
Joseph Boullata, EP
Heather Boux, EC, EP
Marie-Eve Boyte, EP
Cindy Brach, EP
Mike Bradley, EC, EP
Glaucia Karime Braga, EC
Thomas Brendler, EC
Michael Brent, EP
Randolph Breton, EP
Josef Brinckmann, EC
Thomas Broadbent, EC
James Brooks, EC, EP
Janice Brown, EC, EP
Paula Brown, EC, EP
Riekert Bruinink, EC
Lana Bruney, EP
Christopher Bryant, EP
Robert Buice, EC, EP
Richard Burdick, EC
Christopher Burgess, EC, EP (2)
Pierre Burguiere, EP
Matthew Burke, EP
Chris Burns, EC, EP, JS3
Emilia Byrne, EP
Frances Byrne, EP
Tim Cabelka, EC, EP, JS3
Susan Cady, EC, EP
Teresa Cain, EP
Angela Calderon, EC, JS3

Courtney Callis, EP
Robert Cambron, EC
Cristiana Campa, EP
Richard Cantrill, EC, EP (2), JS3
Ishan Capila, EP
Thiago Cardoso Carvalho, EC, EP
Elizabeth (Betsy) Cariello, EC (2)
Brian Carlin, EC, EP (2)
Geoff Carr, EC, EP
Jeffery Carrico, EC
Frederic Carriere, EC, EP
Spencer Carter, EP
Steven Casper, EP
Christophe Cavin, EP, JS3
Richard Cawthorne, EC
Juan Cerdan-Diaz, EP
Wiley Chambers, EP
Chris Chandler, EC
Jane Chang, EP
Yuan-Shiun Chang, EP
Coleman Chasteen, EP
Joseph Chebli, EP
John Chen, EC, EP (2)
Junshi Chen, EC, EP (2)
Pei Chen, EC, EP (2)
Shilin Chen, EC, EP (2)
Hwei-Fang Cheng, EC
Roy Cherris, EP
Edward Chess, CoE, EC, EP, JS3
Anissa Cheung, EP
Kimberly Cheung, EP
Henry Chin, EC, EP, JS3
Grady Chism, EC
Donna Christner, EP
David Christopher, EC
Ian Chung, EC, EP
Shan Chung, EC, EP
Robin Churchill, EC, EP, JS3
Scott Ciarkowski, EP
Mary Lee Ciolkowski, EP
John Cipollo, EP
Roger Clemens, EC
Lucia Clontz, EP
John Clos, EC
Martin Coffey, EC, EP
Michael Cohen, EC
Ewart Cole, EP
Maegen Colehour, EP
John Connelly, EP (2)
Nicole Cook, EP
Frank Corniello, EP
Carrie Coutant, EP
Daniel Crane, EP
Stephanie Crawford, CoE, EC, EP (2)
Richard Creekmore, EC, EP
Bryan Crist, EP (2)
Jill Crouse-Zeineddini, EC, EP (2)
Celia Cruz, EP
Anthony Cundell, EC, EP
Paul Curry, EC, EP (3)
Kevin Dahl, EP
Deirdre D'Arcy, EP
Mike Darj, EP
Helen Darling, EC, EP, JS3
Debashis Das, EC, EP (2)
Nila Das, EC, EP (2)
Vivek Dave, EC
Gigi Davidson, CoE, EC
Cindy Davis, EP
Terry Davis, EP
Josep Maria de Ciurana Gay, EC
Michael De Felippis, CoE, EC
James De Muth, CoE, EC, EP (2)
Mark Decerbo, EC, EP
Lowri DeJager, EP
Sheila Deneau, EC, JS3
Claudio Denoya, EP
Steven Dentali, EC, EP
Allegra DePietro, EP
Radhika Devraj, EP
Jonathan DeVries, CoE, EC, EP (3), JS3
Lawrence Deyton, EP
Thomas DiFeo, EC
Weibing Ding, EP
Maryna Dmitriieva, EP
D.J. Doan, EC
Dennis Doherty, CoE, EC, EP (4)
John Dolan, EC
Gay Dolin, EP
Melanie Downs, EP
Simona Dragan, EC
Sheila Dreher-Lesnick, EP
Gary du Moulin, EP
Alain Duguet, EC
John Duguid, EP
Ian Duncan, EP
Francis Dwulet, EP
Michael Eakins, EC, EP (4)
Andrew Ebert, EC, EP, JS3
Chaim Eidelman, EC
Edmund Elder, EC
Lutz Elflein, EP
Christopher Elkins, EP
Jama Elmi, EC
Mahmoud A. ElSohly, EP
Doreen Elston, EP
Sytze Elzinga, EP
Stephanie Emory, EP
Natalia Epshtein, EC
Ofelia Espejo Gonzalez, EP
Jaap Evers, EC, EP
Mirella Ezban, EC
Raafat Fahmy, EP (2)
Anna Fan, EP
Stephanie Ferrari, EP
Elizabeth Igne Ferreira, EC
Marina Feschenko, EP
Adam Fisher, EP
Sean Fitzgerald, EP
Jonathan Fitzsimmons, EP
Jeffrey Fleitman, EC, EP
Edward Fletcher, EC, EP
Carol Rea Flynn, EP
Daniel Folmer, EP
Ryan Forrey, EC
Mary Foster, CoE, EC, EP
Nikoletta Fotaki, EP
Joe Fotso, EP
Bruce Fowler, EP
Gattas Fred, EP
Tim Freeman, EC
Carl Frey, EC

Olaf Friedrich, EP
Roland Froetschl, EP
Christophe Fuerer, EP
Michael Furness, EP
Stefan Gafner, EC
Sunil Gairola, EP (2)
Wendy Galbraith, EP
Umesh Gangadharmath, EP
Sushil Gangwal, EC
Boyan Gao, EC, EP
Quanyin Gao, EC, EP
Zongming Gao, EC, EP
Norberto Garcia, EP
Thomas Garcia, EP
Diego Garcia Gonzalez, EP
Samuel Gardner, EP
Luigi Ghidorsi, EP (3)
Mary Ghods, EP (2)
Tapash Ghosh, EP (2)
Devinder Gill, EP
Timothy Gilmor, EC
Michel Girard, EC
Lucy Gisonni-Lex, EP
Joseph Glajch, EC, EP (2)
Peter Glassman, EC
Jill Glosson, EP
Yuri Goldberg, EC
David Goldfarb, EC
Lillie Golson, EP
Thomas Gonyon, EP
Carmen Gonzalez, EC, EP
Mario Gonzalez, EC, EP
Jennifer Goode, EP
Dennis Gorecki, CoE, EC, EP, JS3
Catherine Graeff, EP
Rebekah Granger, EP
Gyongyi Gratzl, EC, EP (3)
Elaine Gray, EC, EP (2), JS3
Vivian Gray, EC, EP (2), JS3
Richard Green, EP
Geoffrey Grove, EP
Joerg Gruenwald, EC, JS3
Emanuel Guadagnino, EP
Dana Guazzo, EC, EP
Roy Guharoy, EC, EP (2)
Dennis Guilfoyle, EC
Claudia Guillaume, EP
Mickey Gunter, EP
Dean Guo, EC, EP, JS3
Yin Guo, EC, EP, JS3
Rajesh Gupta, EC, EP
Kathleen Gura, EP
Bill Gurley, EC, EP, JS3
Felicitas Guth, EC
Colleen Guthrie, EC
Gerhard Haas, EC
Morten Hach, EC, EP
Jonathan Hache, EP
Daniel Haines, EP
Takashi Hakamatsuka, EP
Einat Haleva, EC, JS3
Tom Hall, EP
Don Halterman, EP
John Hammond, EC, EP (2)
Faye Han, EP
Jian-Hwa Han, EP
Bruno Hancock, EC
Sukhdev Handa, EC, EP, JS3
Humcha Hariprakasha, EP
James Harnly, EC, JS3
Bruce Harris, EP
Philip Haselberger, EP
James Hathcock, EP
Walter Hauck, EP (2)
Karen Hauda, EC
Douglas Hauke, EP
Robert Hausam, EP
Douglas Hausner, EP
Kan He, CoE, EC, EP
Luhong He, CoE, EC, EP
Xiaorong He, CoE, EC, EP
John Heaney, EP
Ralph Heasley, EC
William Heller, EP
Andre Hermans, EP
John Herries, EC, JS3
William Hess, EP (3)
Anthony Hickey, EC
John Hinshaw, EC, EP
Monica Hirschhorn, EP
Stephen Hoag, EC, EP
Jeffrey Hofer, EP
Lauren Hoffman, EP
Raymond Hohl, EC
Steve Holroyd, EP
David Hopp, EC, JS3
Michael Hornig, EP
Christopher Hosty, EP
Kate Houck, CoE, EC, EP
Deborah Houston, EC, EP
Keith Howard, EP
Xiao Ping Huang, EP
Mario Hubert, EC
Christopher Hudalla, EP
Ruud Hulspas, EP
Gregory Hunter, EP
Munir Hussain, EC, EP
Stephen Hussey, EP
David Hussong, CoE, EC, EP
Kim Huynh-Ba, CoE, EC, EP (4), JS3
Chung Hyun, EC
John Iannone, EP
Karthik Iyer, EC, EP
Rupa Iyer, EC, EP
Scott Jackson, EP
Thomas Jacques, EP
Monika Jain, EC
Vincent Jannin, EP
Renaud Janssen, EC, EP (2)
Edwin Jao, EP
Arya Jayatilaka, EC
Eric Jayjock, EP
Dennis Jenke, EC, EP (2)
Matthew Jenkins, EP (2)
Brenda Jensen, EC, EP
Keith Jensen, EC, EP
Anne Jespersen, EC, JS3
Shen Ji, EP
Kristian Johansen, EP
Bruce Johnson, EC, EP
Holly Johnson, EC, EP
Kent Johnson, EC, EP

Philip Johnson, EC, EP
Chris Jones, EC, EP (3)
Jacquin Jones, EC, EP (3)
Michael Jones, EC, EP (3)
Scott Jordan, EC, EP, JS3
Joy Joseph, EC
Eliangiringa Kaale, EP
Ravi Kalyanaraman, EP
Mahendra Kapoor, EP
Amy Karren, CoE, EC
Ravindra Kasliwal, EP (2)
Greg Kaster, EC, JS3
Joe Katzenmeyer, EP
David Keire, EP
David Keller, EP
Michael Kennedy, EP, JS3
Shaun Kennedy, EP, JS3
James Kenney, EP
Zohar Kerem, EP
Eric Kesslen, EC, EP
Sridevi Khambhampaty, EC
Ikhlas Khan, EC, EP (2), JS3
Johannes Khinast, EP (2)
Surender Khurana, EP
Douglas Kiehl, EC, EP (2)
Patricia Kienle, EC, EP
John Kilbourne, EP
Yeong Shik Kim, EP
Kathryn King, EC, EP, JS3
Marion King, EC, EP, JS3
Stephen King, EC, EP, JS3
Jonathan Kingsbury, EP
Heinz Kirchmeyer, EP
Duane Kirking, EC, EP
Robert Klasson, EC
Sandra Klein, EP
Brent Kleintop, EC, EP
Katrina Klett, EP
Lori Klopf, EC
Richard Ko, EC, EP (2), JS3
Michael Koberda, EC, EP
Andreas Koerner, EP
Hwee-Ling Koh, EP
Otilia Koo, EC
Hemant Koshia, EC
Satyanarayana Kota, EP
Pramod Kotwal, EP
Elisabeth Kovacs, EP (2)
Johannes Kraemer, EC, EP
Elizabeth Kramer, EP
Jette Kreiberg, EP
Jens Krogh Rasmussen, EP
Thijs Kroon, EP
Dana Krueger, EC, EP (2), JS3
Markus Krumme, EP
Scott Kuhns, EP (2)
Jeremy Kunkel, EC, EP
Francisco Kuribrena, EP
Joseph Kutza, EP
Wilberforce Kwiringira, EP
Pauline Lacroix, EC, JS3
Michael Laird, EP
Kim Lamey, EP
Thomas Langdon, EP (2)
Gerd Langenbucher, EP
David Lansky, EC, EP
Gregory Larner, EP
Peter Larsson, EC
Clara Lau, EP
Max Lazar, EP
Dave LeBlond, EC, EP
Pierre Lebrun, EP
Hyoung Lee, EP
Patricia Lee, EP
Sau Lee, EP
Michele Lees, EP, JS3
Russell Leftwich, EP
Philippe LeGall, EP
Steven Leinbach, EC, EP
Stefan Leiner, EC, EP
Patrice Leone, EP
Nancy Lewen, CoE, EC, EP (3)
David Lewis, EC, EP
Jerome Lewis, EC, EP
Todd Lewis, EC, EP
Hanlin Li, EP
Huijuan Li, EC, EP
Min Li, EC, EP
Ping Li, EC, EP
Qing Li, EC, EP
Judy Lin, EC
Oscar Liu, EC, JS3
Rosario Lobrutto, EP
Paul Lockwood, EP
Raimar Loebenberg, EC
William Long, EC
Archie Lovatt, EP (2)
Raymond Love, EC, EP
Vivian Loveless, EP
Tieraona Low Dog, EC, EP, JS3
Xujin Lu, EP
Shuangcheng Ma, EP
Wendy Mach, EC, EP
LeeAnn Machiesky, EP
Andrew Mackey, EP
Donald MacLean, EC
Russell Madsen, EC, EP
Paul Mahan, EP
Patrick Mahn, EP
Amir Malek, EP
Dan Malinowski, EC
Annarapu Malleswarareddy, EC, EP
Brad Mangrum, EP
Rezaul Mannan, EP
Jaime Marach, EP
Robin Marles, CoE, EC, EP (2), JS3
Ewa Marszal, EP
Gregory Martin, EC, EP (4)
Jerold Martin, EC, EP (3)
Marilyn Martinez, EP
Nuno Matos, EC, EP
John Mauger, EC, EP (2)
Russell Maus, EC
Joan May, EC, EP
Robert Mayer, EC
Lori McCaig, EP
Robert McClure, EP
Diane McColl, EC
Karen McCullough, EC
Gerald McEvoy, EP (3)
Timothy McGovern, EP (2)
Pauline McGregor, EC, EP

Kevin McLean, EP
Jeffrey Medwid, EP
Juris Meija, EC
Jeremy Melanson, EP
Armen Melikian, EC
Robert Mello, EC
Phil Merrell, EC
Richard Meury, EC, EP
Marian Meyer, EC
Steven Meyerhoffer, EP
Yana Mille, EP (2)
Kenneth Miller, EC, EP
Michael Miller, EC, EP
Paul Miller, EC, EP
Colin Minchom, EC
Beth Minter, EC
Anthony Mire-Sluis, EC, EP
Jolyon Mitchell, EC (2)
Ashim Mitra, EP
William Mixon, EC
Adil Mohammad, EP
Felix Montero Julian, EP
Dominic Moore, EC
Richard Moreton, EC, EP (2), JS3
Magdi Mossoba, EP
Ned Mozier, EC, EP, JS3
Michael Mulkerrin, CoE, EC
Matthew Mullarney, EC
Pierre-Alain Muller, EC
Barbara Mulloy, EP (2)
Eric Munson, CoE, EC
Kelly Murphy, EP
Leanne Murray, EP
Jasmine Musakhanian, EC, EP
John Musil, EC
Fernando Muzzio, EP
Richard Myers, EC, JS3
Dattatraya Naik, EP
Prabu Nambiar, EC, EP
Linda Narhi, EP
Tanja Natterer, EP
Mirtha Navarro, EC, EP
Victor Navarro, EC, EP
James Neal-Kababick, EC, EP (2), JS3
Sesha Neervannan, EP
Phil Nethercote, EC, EP
Mariann Neverovitch, EC
David Newton, EC, EP
Paul Newton, EC, EP
Juliet Nguyen, EP
Nina Ni, EP
Cornelia Nickenig, EP
Ishai Nir, EP
Pallavi Nithyanandan, EP
Patrick Noland, EC
Anna Nordin, EP
Daniel Norwood, EC, EP (2)
Jasmina Novakovic, EC, JS3
Adrian Nunn, EP
Thomas O'Connor, EP
Anthony Okinczyc, EC
Bernard Olsen, CoE, EC, EP (2), JS3
Raphael Ornaf, EC, JS3
Todd Osiek, EP
Robert Osterberg, EC, EP
Mary Paine, EP
Pilar Pais, EC, EP
Anthony Palmieri, EP
Marco Pane, EP
Mark Papich, EC, EP
Ajay Parashar, EC
Bhavin Parekh, EP (2)
Ernest Parente, CoE, EC, EP
Jose Parisi, EP
Ruth Parker, EP
Jonathan Parks, EC
Bruna Parma, EP
Alan Parr, EC, EP
Richard Parrish, EP
Donald Parsons, EC
Diane Paskiet, EC, EP (2)
Dhananjay Patankar, EC, JS3
Brij Patel, EP
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