Report to the Board of Trustees on

Council of Experts Activities

Fiscal Year Report

2021

Our successes in FY 18 were made possible by the numerous hours—estimated at more than 127,000—that were generously contributed by our Expert Volunteers and augmented by our dedicated staff."

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 third annual report of the 2015–2020 cycle on the activities and achievements of the CoE, its Expert Committees (ECs), and its Expert Panels for fiscal year 2018.

We have made great progress that will continue into FY 2019 and beyond, to USP's 2020 Convention and the 200th anniversary of the founding of USP.

A key focus last fiscal year was the continuation of preparations for the next Convention cycle, for which we reached two major milestones: the Call for Candidates (C4C) and the CoE structure for 2020–2025. The C4C launched in mid-2018 with an entirely novel approach. For the first time, the C4C is enabling the next generation of volunteers to express their interests in areas of expertise instead of specific ECs. This will enable USP staff and elected chairs to more effectively match qualified applicants with USP's needs for Expert Volunteers and volunteer bodies that will lead us into the future. I encourage current and prospective volunteers to apply as early as possible. By the same token, the current CoE has proposed the number and types of ECs for the 2020–2025 cycle, including the addition of five new ECs that aim to address current and new scientific challenges.

I want to highlight five of the many notable accomplishments in FY 18.

First, the Biologics program successfully initiated the development of performance standards that support product families or classes, or technologies, throughout the product lifecycle. The first set of critical performance standards, including several that support monoclonal antibody characterization, is currently underway.

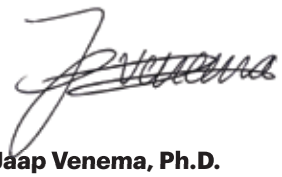
Second, the Compounding EC revamped its approach in an effort to align its standards, in terms both of general chapter content and timeline. The intent is to remove all duplicative information from General Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations,* <797> *Pharmaceutical Compounding—Sterile Preparations,* and <800> *Hazardous Drugs—Handling in Healthcare Settings*.

Third, significant progress has been made in identifying a sustainable path for developing standards for over-the-counter (OTC) products. USP staff convened and collaborated closely with representatives of the US Food and Drug Administration (FDA) and the Consumer Healthcare Products Association, a national trade association representing OTC manufacturers and marketers. The discussions focused on the need to create a flexible monograph development approach for the vast number of OTC products covered under FDA OTC monographs, as well as the myriad formulations on the market.

Fourth, the first major milestone in our five-year Up-to-Date (U2D) effort was the completion of the Reference Standard U2D program, which assessed the quality of USP's entire catalog of Reference Standards to ensure their suitability for use now and into the future. As a result of this program, USP has adapted and, where necessary, increased the Reference Standard testing schedules and methods.

Fifth, the successful completion of a change to the *Rules and Procedures of the CoE* on June 1, 2018, allows the CoE to delegate to USP staff the authority to approve limited routine documentary standard revisions and omissions. Going forward, EC members can now focus on the complicated and resource-intensive standards that require more value-added scientific deliberations, expert evaluation, and judgment. A guideline and internal work instruction were created to ensure that these revisions are properly handled and processed.

Our successes in FY 18 were made possible by the numerous hours—estimated at more than 127,000—that were generously contributed by our Expert Volunteers and augmented by our dedicated staff. Thank you for your commitment to USP's mission. I warmly invite you to read the following pages, which tell the story in greater detail of how USP's accomplishments benefit patients, consumers, 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

Fostering Collaboration

FY 18 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 are aligned with USP's Resolutions, policies, and strategies. The CoE oversees the activities of more than 750 global scientific experts who serve on ECs, Expert Panels, 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 reference materials.

USP Governing Bodies

Board of Trustees (BoT)

13 members elected by Convention and USP CEO responsible for:

- USP policies
- Finances
- Strategic direction

USP Convention

458 organizations invited by Council of Convention and BOT responsible for:

- Resolutions that guide USP policies and initiatives
- Electing BOT/CoE

Council of Experts (CoE)

25 chairs of USP ECs elected by Convention plus the USP Chief Science Officer who serves as CoE Chair, responsible for:

- USP scientific and standards-setting decisions
- Standards-setting work of USP's volunteer scientific expert groups
- Adhering to direction set forth by BoT and Convention

Volunteer Groups Under CoE

ECs

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

Expert Panels

Advisory bodies formed to supplement EC expertise on specific topics. Have specific charge and are dissolved upon completion of work. Members may be EC members or serve on multiple Expert Panels.

JS3s

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

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

USP Standards Approved in FY 18

Expert Volunteers play a vital role in approving standards, both documentary for publication and reference standards for release. Expert Volunteers ballot on all regular documentary standard revisions, new reference standards, and on a sampling of replacement and continuation lots.

Documentary Standards		Reference Standards	
486 new or revised documentary standards	179 modernized *United States Pharmacopeia and National Formulary (USP–NF)* and *Food Chemicals Codex (FCC)* monographs	81 new Reference Standards (F lots)	509 released replacement and continuation (R&C) lots of Reference Standards

FY 18 Balloted & Approved Standards by Compendia and Type

	# of Ballots	Items Balloted	New	Revised	Omitted	Modernized
***USP–NF* Book/Supplement Total**	**49**	**456**	**55**	**231**	**48**	**172**
USP 41–NF 36, First Supplement (1S)	15	106	21	71	14	54
USP 41–NF 36, Second Supplement (2S)	17	160	23	67	7	59
USP 42–NF 37	17	190	11	93	27	59
***FCC* Book/Supplement Total**	**2**	**20**	**1**	**19**	**0**	**7**
FCC, 11th Edition	1	4	0	4	0	0
FCC, 11th Edition, 1S	1	16	1	15	0	7
Accelerated Revisions	**39**	**71**		**71**		
July 2017	8	20		20		
September 2017	4	9		9		
November 2017	2	4		4		
December 2017	4	4		4		
January 2018	5	10		10		
February 2018	2	2		2		
March 2018	3	4		4		
April 2018	4	11		11		
May 2018	4	4		4		
June 2018	3	3		3		
Nomenclature	**109**		**109**			
Reference Standards R&C	**8**					
BIO and *FCC* F Lots	**3**					
Harmonization	**2**					
Herbal Medicines	**0**					
Total	**212**	**547**	**165**	**321**	**48**	**179**

FY 18 Key Activities & Accomplishments

The CoE met six times during FY 18, focusing on the following high-level priorities

Over-the-Counter (OTC) Product Standards: In collaboration with the FDA and the Consumer Healthcare Products Association, the Chemical Medicines Monographs 6 EC made significant progress in identifying a path forward for developing standards for OTC products. This includes the formation of the OTC Drug Products Working Group as well as a sub-team to address OTC-related issues. Discussions have included approaches that are flexible for industry and also support regulatory and compliance requirements to ensure product quality.

General Chapter <11> *USP Reference Standards:* The CoE finalized a draft revision of General Chapter <11>, which addresses the types, applications, and uses of USP Reference Materials cited in *USP–NF* standards. The CoE Working Group on General Chapter <11> agreed that the scope of <11> should center on the main compliance uses of Reference Standards but should also include the policy basis for other measurements, and that USP should remove the 100% content assumption for Reference Standards in <11> and General Notices, Section 5.80. USP Reference Standards.

2020–2025 CoE and Its EC Structure: The CoE continued to evaluate the potential future structures and roles of the USP standards-setting volunteer bodies and of the Council itself in the next cycle. The CoE has considered numerous recommendations, including the possibility of forming new ECs. The proposed structure is open for Convention comments; the Board of Trustees will vote on the structure at its November 2018 meeting.

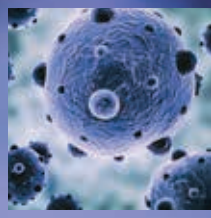
Reimagining the Collaborative Groups (CGs): The CoE explored ways to reinvent CGs, including new approaches for better communication and collaboration between ECs on cross-cutting topics. CGs currently consist of chairs and vice chairs and are mainly used for sharing information, not for making decisions or recommendations. Under one potential model, CGs could comprise at least one chair and members of other ECs who can share expertise on specific issues. These issues could be priority items for a product class, such as OTCs within chemical medicines, or other high-impact, cross-cutting topics, such as elemental impurities, that have policy implications beyond a specific, narrow area.

USP Staff Rule 7.06 Change: On June 1, 2018, a revised section of the *Rules and Procedures of the Council of Experts* (*CoE Rules*) became effective, allowing the CoE to delegate to USP staff the authority to approve limited documentary standard revisions and omissions. This change was made to reduce the burden on EC members of balloting on standards that generally do not require EC evaluation, such as revisions that accommodate newly approved manufacturers with expanded specifications. This will allow EC members to focus on more complicated and resource-intensive standards and revisions for which expert evaluation and judgment are necessary. Delegating to USP staff the task of approving these revision types will also permit more expeditious approval and publication of clear-cut compliance-based revisions and help USP achieve Up-to-Date across the compendia. The CoE also approved a separate document, *Guideline for USP Staff Approval of Limited Documentary Standard Revisions and Omissions,* which outlines the criteria for revisions that can be approved by USP staff. In addition, an internal work instruction was created for USP staff to ensure that these revisions are properly handled and processed. USP staff began implementing this change in July 2018.

The CoE explored ways to reinvent CGs, including new approaches for better communication and collaboration between ECs on cross-cutting topics... Under one potential model, CGs could comprise at least one chair and members of other ECs who can share expertise on specific issues.

Biologics

The Biologics program invested resources to increase awareness of USP's role in biologics and engaged with key stakeholders to address unmet needs in the performance of analytical applications. Areas of focus cover existing products (e.g., therapeutic proteins such as monoclonal antibodies and enzymes) and emerging products developed based on novel technologies (e.g., cell and gene therapies, and nucleic acid–based therapies such as genetically engineered T cells). Additionally, the Biologics program invests in the maintenance and growth of existing standards that cover peptides, proteins, blood products, vaccines, antibiotics, carbohydrates, tissues, and raw materials used in biologics manufacturing. The Biologics program works to fulfill Resolution VI, which calls for USP to promote alignment with stakeholders to develop quality standards for biological medicines.



"We have transitioned monographs that cover the antibiotics using microbial assays for activity measurement to the Biologics Collaborative Group, culminating in the launch of a dedicated Expert Committee, Biologics Monographs 4–Antibiotics."

Pascal Anger, Ph.D.
Chair, Biologics Monographs 4–Antibiotics (BIO4) EC

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

"The BIO3 EC face-to-face meeting hosted a presentation from Trevor Broadt, Ph.D. (Frederick National Laboratory for Cancer Research), a thought leader on challenges in cellular and gene therapies. Dr. Broadt discussed challenges faced in viral product development and the industry's need for well-characterized reference materials for gene therapy, vaccine, and oncolytic viral products. Dr. Broadt's insights led to EC discussions of challenges and potential development of industry-needed standards in the rapidly emerging areas of cellular and gene therapies."

FY 18 Key Activities & Accomplishments

Roundtables: To engage industry in compendial activities, USP co-sponsored the USP Biologics and Biotechnology Innovation Organization Roundtable on Performance Standards Development, held October 24, 2017, at USP–US, Rockville, and the USP Biologics and International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Roundtable on Performance Standards Development, held May 31, 2018, at the Renaissance Marriott Hotel in Vienna, Austria. These roundtables brought together stakeholders from leading pharmaceutical companies and the US Food and Drug Administration (FDA) to discuss performance standards development. Performance standards are vital in supporting quality control, analytical development, process development, and comparability of assays and materials between companies. USP successfully engaged with industry to identify areas of mutually beneficial collaboration, thereby identifying and prioritizing standards based on development feasibility and benefit to industry, and reaffirmed its ongoing commitment to partnering with its stakeholders in the development of performance standards.

Workshops: USP's 7th Bioassay Workshop, held November 25–26, 2017, at USP–US, Rockville, gave attendees the opportunity to consider and discuss lifecycle methods from scientific, statistical, and regulatory perspectives, including the presentation of case studies from various stages in an assay's lifecycle. USP held its 4th annual Therapeutic Peptides Workshop on November 6–7, 2017, at USP–US, Rockville, with an in-depth program examining GMP manufacturing considerations; analytical characterizations; chemistry, manufacturing, and controls (CMC); and formulation for diverse delivery systems.

Performance Standards: These standards are used to demonstrate analytical and process performance throughout the biologics product lifecycle. Performance standards may or may not be tied to a monograph and will be accompanied by a separate dataset or application notes. The program focused this year on the identification and prioritization of standards applicable to therapeutic proteins. Candidate materials have been identified and sourced by USP, and proof-of-concept studies are underway in USP laboratories. USP staff engaged with Expert Committees (ECs) to confirm relevance of the standards under development and identified the processes needed for timely delivery.

First Cell-Based Assay for Insulin Products: Development of the first cell-based assay for insulin products was a major achievement of the Insulin Expert Panel of the Biologics Monographs 1–Peptides (BIO1) EC. The cell-based assay will provide an alternative to the animal assay, and it aligns with USP's commitment to reduction, refinement, and replacement of animal testing.

Fouad Atouf, Ph.D.
Vice President, Science, Global Biologics

"When patients with leukemia or other conditions need a bone marrow transplant, treatment success depends on choosing a viable transplant sample with the right amount of blood stem cells to rebuild the immune system. That's a key reason we are very proud of our work on the CD34+ Cell Enumeration System Suitability Reference Standard. This standard is used by laboratories involved with enumeration of stem cells derived from bone marrow, cord blood, or peripheral blood, and the cell count will inform practitioners on the number of cells a patient will receive. In addition to stem cell transplants, the test is also used by researchers working with patients in clinical trials for new life-saving treatments."

"The BIO1 Expert Committee has made great progress in modernizing existing monographs related to peptides. To support these updated documentary standards, BIO1 approved several new Reference Standards and is exploring potential performance standards related to impurities. In addition to progress on its Work Plan, BIO1 engaged with FDA and industry stakeholders providing feedback intended to advance standards development for this important therapeutic class."

Michael DeFelippis, Ph.D.
Chair, Biologics Monographs 1–Peptides EC

FY 18 Highlights: Biologics

- 1 New General Chapter
- 1 Revised General Chapter
- 2 General Chapters Published for Public Review in *Pharmacopeial Forum* (*PF*)

- 3 New Monographs
- 8 Revised Monographs
- 9 Monographs Published for Public Review in *PF*

- 20 Reference Standards Released

Chemical Medicines

Bruk Alemayehu, MBA
Vice President,
Chemical Medicines

"In FY 2018, USP collaborated with the FDA as we seek to support FDA's Drug Competition Action Plan and we are exploring compendial approaches and resources including development and revision of monographs for products that lack generic competition. We continue to engage with FDA and industry to help establish flexible compendial pathways for OTC monographs that meet both industry and FDA's needs and advance medicine quality. We also collaborated with FDA and instrument manufacturers to validate and develop various OTC monograph methods."

Chemical Medicines is responsible for developing and revising monographs for drug substances and drug products. Chemical Medicines continues to increase and broaden its communication and collaboration with the FDA and its USP EC government liaisons on monograph development and validation, in alignment with Resolution I, through programs such as the Cooperative Research and Development Agreement (CRADA), Confidential Disclosure Agreement (CDA), and the FDA Over-the-Counter (OTC) Drug Products Working Group.

FY 18 Key Activities & Accomplishments

Collaboration With the FDA: In FY 18, under the CRADA program, seven monograph modernization projects were completed, including high-impact OTC dentifrices and dermatology products. In collaboration with the FDA OTC Working Group, USP developed two new OTC monographs for cough and cold products. FDA continuously provides input on monograph development through active participation of FDA government liaisons in the standards-setting process.

OTC Medicines: In USP's ongoing efforts to protect the quality of OTC medicines as well as patient access to them, USP works with the FDA and industry through the Consumer Healthcare Products Association (CHPA) to update the USP OTC monograph portfolio. These three groups have formed the OTC Drug Products Working Group to address OTC drug product monograph-related challenges. In FY 18, USP hosted two successful OTC Drug Products Roundtable Retreats (September 19, 2017, and March 15, 2018), with FDA and CHPA in attendance, to discuss joint efforts on advancing the quality of USP OTC product monographs and identify practical and acceptable standards implementation. In addition, a team of Chemical Medicine Scientific Liaisons successfully engaged multiple instrument manufacturers to support monograph modernization efforts.

***United States Pharmacopeia and National Formulary (USP–NF)* Monograph Modernization:** In alignment with Resolution II, Chemical Medicines continues to work toward modernization of the *USP–NF* through collaboration with the FDA and industry.

General Chapter <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging:* In response to comments to the 2015 revision of <797> *Pharmaceutical Compounding—Sterile Preparations,* the Chemical Medicines 4 EC convened an Expert Panel tasked with developing a general chapter to specifically address processing of radiopharmaceutical products. The Expert Panel developed General Chapter <825>, which will be published in *PF* 44(5) [Sep.–Oct. 2018] for public comment.

Chemical Medicines developed monographs for drugs that use non-oral or parenteral routes, including those used to treat asthma, migraine, Parkinson's disease, and smoking cessation. Having USP monographs for these products will facilitate generics coming to market, giving patients and doctors diverse choices for treatments.

FY 18 Highlights: Chemical Medicines

49 New Monographs
226 Modernizations
177 Omissions

Among the revisions Chemical Medicines worked on in FY 18, the development of the new General Chapter <825> will have significant impact. Prior to the development of <825>, nuclear pharmacists engaged in compounding were required to follow the procedures described in General Chapter <797>, which does not address radiation-specific safety practices, leading to deviations from strict adherence to <797> handling conditions and practices. General Chapter <825> addresses these problems by being specific to radiopharmaceuticals, allowing healthcare providers to dose patients with radioactive drugs compounded using dedicated procedures."

Domenick Vicchio, Ph.D.
Director, Science – Chemical Medicines

Chemical Medicines modernized the tetrahydrozoline hydrochloride drug substance monograph and the ophthalmic solution drug product monograph. This work was of high priority to us as it aligns with the demand for enhancing OTC product quality and improving patient safety. It is very satisfying to have contributed to USP's mission of protecting public health by providing the manufacturers with a better understanding of the critical quality attributes and providing the regulators with more clearly defined standards and procedures for enforcement."

Leonel Santos, Ph.D.
Director, Science – Chemical Medicines

Dietary Supplements & Herbal Medicines

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*. The development of a database that addresses dietary supplements (DS) adulterated with undeclared drugs or drug analogues is underway. In FY 18, collaborations with the Food Ingredients (FI) EC increased substantially on issues related to ingredient nomenclature, safety evaluation, and modernization of compendial methods for identity and purity.

FY 18 Highlights: Dietary Supplements & Herbal Medicines

- 32 New Dietary Supplement Monographs
- 15 New *Herbal Medicines Compendium* Monographs
- 11 Modernized Monographs
- 43 Revised Monographs
- 8 Omitted Monographs

FY 18 Key Activities & Accomplishments

DS Workshops: In collaboration with the FI team, the DS team led a workshop at USP–US, Rockville, on February 28 to March 1, 2018, regarding adulteration and fraud in FI and DS. An international cadre of scientists—including those from the FDA and the European Commission—discussed technology, described case studies, and participated on panels. The DS team also co-hosted a workshop on probiotic quality with the International Probiotics Association at USP–US, Rockville, on December 4–5, 2017. Key issues discussed at the workshop that have potential health impacts include industry support for development of specifications as well as for appropriate labeling for viability at end of shelf life.

Limits for Pesticide Residues: USP and BDSHM EC representatives met with the Environmental Protection Agency (EPA) to discuss the role compendial specifications could play in addressing gaps in regulations regarding the limits for pesticide residues in botanical DS.

DNA-Based Identification: The USP Project Team on Botanical Library for DNA-Based Identification has identified priority botanicals and provided multiple lots for building a botanical library. This work will also support efforts to develop species-specific test methods. Method development and market research are underway to assess the challenges involved with DNA-based methods and stakeholder needs. This project has potential to contribute to the cross-functional programs of biologics, foods, and probiotics by keeping USP standards up to date and by demonstrating responsiveness to stakeholder needs.

Cannabis Standards: In response to scientific inquiries from states, regulatory agencies, and science organizations, USP is continuing to act as a resource and as a technical advisor, including work with ASTM and Health Canada.

Green Tea Extract Hepatotoxicity (GTEH): Collaboration continued between the GTEH Expert Panel and the Drug-Induced Liver Injury Network (DILIN) to obtain their expert evaluations of causality for reported cases of liver injury reputed to be associated with intake of concentrated green tea extracts. The DILIN component is almost finished, which will allow the GTEH Expert Panel to prepare its final report for submission first to the BDSHM EC for review and then to the CoE.

DS Stakeholder Forum: Manufacturers, organizations, service providers, and others who work with DS discussed issues and shared perspectives related to USP DS standards at the Stakeholder Forum on DS, held May 15, 2018, at USP–US, Rockville. USP staff gathered feedback on current and future standards-setting efforts and updated attendees on the following projects and initiatives: 1) development of a glossary of commonly used USP terms, 2) flexible adoption of modern procedures in USP standards, 3) continued engagement with industry and regulators to advocate for broader adoption of limits for pesticide residues in <561> *Articles of Botanical Origin*, 4) USP engagement with the DS Quality Collaborative, and 5) the USP adulterants database (Roman Database). USP staff and EC members also provided updates on the progress in ongoing standards development activities related to quantitative nuclear magnetic resonance (qNMR), probiotics standards, cranberry standards, DNA-based methods for botanical identification, proteins, chewable gels (gummies), residual solvents, and bioavailability.

Publications: The USP DS botanical team published an article, "Quality Specifications For Articles of Botanical Origin from the United States Pharmacopeia," in *Phytomedicine*. It is hoped that the article will increase stakeholder understanding of USP botanical monographs and will help stakeholders establish suitable quality control methods for botanicals. In addition, BDSHM EC members and USP staff published an article, "Cinnamon and Cassia Nomenclature Confusion: A Challenge to the Applicability of Clinical Data," in *Clinical Pharmacology & Therapeutics,* which discussed USP standards for cinnamon and cassia that can help resolve this issue.

"Our highest public health impact monograph this year is the multiple micronutrient powder (MNP), Vitamins with Minerals Oral Powder. MNPs are designed for point-of-use fortification of foods for children and vulnerable populations to address anemia as well as vitamin and mineral deficiencies. The monograph was designed for UNICEF to serve as an international standard for MNPs."

Kit Goldman, Ph.D.
Director, Dietary Supplements & Herbal Medicines – Science

Robin Marles, Ph.D.
Chair, BDSHM EC

"To better address Resolution II, *USP–NF* monograph modernization, we formed a Modern Analytical Methods Joint Subcommittee together with our sister NBDS EC and FI EC colleagues. The objective is to develop flexible monographs with validated alternative analytical methods using more modern technology such as ultra-performance liquid chromatography, chemometric fingerprinting, and qNMR. When such changes to monographs are presented in the *PF*, they will be accompanied by a business impact/return on investment analysis to show that they are not only scientifically fit-for-purpose but also economically practical alternatives."

Excipients

Bringing excipient monographs up to date is a top priority of the Excipient Monographs ECs. Working closely with the FDA and industry stakeholders, the ECs are using both internal and external resources to improve the analytical testing that exists in USP excipient monographs. As the newly introduced tests often give much more detailed information about the excipient composition, the monographs must be updated to reflect this new knowledge. In some circumstances, limits may need to be changed or added to reflect the true composition of the excipient. The challenges of translating this knowledge into improved monograph standards has been highlighted in a recent *Stimuli* article written by the Excipients Impurities Joint Subcommittee composed of members of both Excipient Monograph ECs and USP Scientific Liaisons. In addition to monographs, improving and adding general chapters related to excipients remain top priorities of the Excipient ECs."

Eric Munson, Ph.D.
Chair, Excipient Monographs 1 EC

USP's Excipient Monographs 1 and 2 ECs continued to address the challenges of updating excipient monographs to ensure that they are fit for purpose and to address potential threats from the complexities of global supply chains. These two ECs are revising their strategy for fulfilling Resolutions II and III, which call for up-to-date and harmonized standards to benefit all stakeholders.

FY 18 Key Activities & Accomplishments

Up-to-Date: The Excipient Monographs ECs continued to support this major initiative by prioritizing a pipeline of high-impact missing monographs as well as monographs slated for update. To that end, USP has committed additional Scientific Liaison and Strategic Customer Development resources at the USP–India site.

Excipient Composition and Impurities: The Excipient Impurities Joint Subcommittee published a *Stimuli* article in *Pharmacopeial Forum (PF)* 44(3) [May–Jun. 2018] titled "The Complexity of Setting Compendial Specifications for Excipient Composition and Impurities." A survey was launched concurrently to obtain feedback from stakeholders on the idea of developing an informational general chapter numbered above 1000 on excipient composition and impurities.

External Engagement: The Pharmacopeial Discussion Group (PDG) meeting was held at USP–US, Rockville, on September 12–13, 2017. During this meeting, PDG agreed to the implementation of significant changes to the harmonization working procedure, as well as in-depth discussions on a number of additional items currently on the revised work program. These efforts should facilitate the resolution of outstanding issues and the advancement of these items toward approval.

Novel Excipients: USP is drafting a policy position on novel excipients, a key component in the development of safer and more effective drugs.

Excipients Strategy: The Excipient Monographs EC chairs identified a need to hold a strategy meeting to discuss high-level topics. These discussions will support the Excipient Monographs ECs in developing strategies and plans to guide decisions for the next five to 10 years, and will help address recurring topics while prioritizing the Work Plan.

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

Most people don't think much about excipients, which are considered the 'inactive' ingredients in medicine. But these are actually critically important to how well a drug works in the body, as well as how it tastes if it's oral medication. And they can cause great harm to patients if their quality is poor, so we are very proud of the work we do to help ensure the quality of excipients. We published draft standards seeking comments from international stakeholders revising the standards for three types of saccharin. Today, saccharin is used is help make medicines—which would otherwise taste pretty bad—palatable for patients. It is also used as an excipient for medications delivered intravenously or by aerosol, which means it's critical to control impurities. This work is important because we know that saccharin may contain about 10 impurities that can develop during some manufacturing processes, including a few that can be harmful. This is part of our work with the Pharmacopeial Discussion Group, which includes *USP*, the *European Pharmacopoeia*, and the *Japanese Pharmacopoeia*, to harmonize excipient monographs and general test methods in order to align standards to bring more efficiency in quality testing."

FY 18 Highlights: Excipients

- 6 Stage 4 (former Stage 6) Postings on USP.org
- 1 *Stimuli* Article and Associated Survey
- 5 F Lots
- 40 R/C Lots
- 6 PDG Monographs Published for Public Review in *PF* Harmonization Section
- 4 Harmonized PDG Monograph Sign-Offs
- 13 Monograph Modernizations in *USP–NF*
- 20 Monograph Modernizations and 1 General Chapter Published for Public Review in *PF*

Food Ingredients

"In FY 18, we continued work on developing high-impact ingredient standards, on methods guidance, on increased collaboration with other standards-setting bodies, and our ongoing efforts to modernize the standards and methods in the *Food Chemicals Codex*. This year the foods program completed a major strategy review leading to a renewed focus on standards and standards-setting activities. To provide the resources to implement this strategy we have discontinued our food fraud services and have moved the Food Fraud Database to a new home where it will continue to be a growing and impactful resource for the food industry and regulators."

Steve Gendel, Ph.D.
Senior Director
Science – Foods

USP's 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 Dietary Supplements ECs to coordinate the development of standards for substances that are used as both dietary and food ingredients. In accordance with Resolution X, which relates to food quality and integrity, the FI EC works to identify and address emerging concerns related to new production technologies, new ingredients, and the globalization of the food supply.

FY 18 Key Activities & Accomplishments

Dietary Proteins (DP) Expert Panel: The FI EC formed a DP Expert Panel to develop, validate, and recommend new DP specifications, analytical tests, and related scientific documents. DP ingredients usually merit premium prices and are traded at high volume, rendering them particularly susceptible to economically motivated adulteration that current standards may not detect. New or modernized USP standards will help identify adulterated dietary proteins, thereby protecting public health and improving confidence in the global food supply.

Food Adulteration (FA) Expert Panel: The FA Expert Panel continued work on revising and extending the Food Fraud Mitigation Guidance that appears in the *FCC*. The Panel focused on user feedback regarding the need for tools to identify high-priority ingredients in facilities that use a large number of ingredients, where it would be impractical to complete a full vulnerability assessment for all of the ingredients.

Honey Expert Panel: The FI EC formed a Honey Expert Panel to develop, validate, and recommend new analytical tests and specifications for honey. Honey is susceptible to adulteration (including full replacement) with cheaper sweeteners as well as with products potentially containing unlawful and unapproved veterinary drug and pesticide residues and adulterants. Authentication of pure honey is important to consumers and processors.

Olive Oil Authenticity and Quality (OOAQ) Expert Panel: The OOAQ Expert Panel continued its work on drafting a proposed Identity Standard for Olive Oil, Refined, which will appear in the December 2018 *FCC Forum*. The Expert Panel discussed plans for creating similar identity standards for other olive oil products, which will be addressed after finalization of the Olive Oil, Refined standard.

Collaboration With Codex Alimentarius: The FI EC continued to collaborate with the Codex Committee on Food Import and Export Inspection and Certification Systems to develop a discussion paper on food adulteration. The EC also collaborated with the Codex Committee on Food Hygiene on a Code of Practice for Allergen Management for Food Business Operators.

FY 18 Highlights: Food Ingredients

3 F Lots
13 R Lots
7 C Lots

8 New Monographs
29 Revised Monographs
13 Modernized Monographs

The FI EC proposed a new monograph for galacto-oligosaccharides (GOS), a class of ingredients commonly considered "prebiotics" used as a source of fiber in foods for special nutritional purposes, including infant formula. The development of a standard for these ingredients has been challenging because each manufacturer's product differs in the profile of specific GOS. In addition, separating and quantifying the specific GOS present is difficult, and this standard required a great deal of development work by the USP laboratory in China. The standard is meant to be used for different types of GOS products on the market and will help food formulators confirm the specific types of GOS present in the ingredients they purchase.

The FI EC proposed a new test for Determination of Starch and Starch Degradation Products in Skim Milk Powder (SMP) and Nonfat Dry Milk. Its development was driven by a desire to create and validate an analytical method that could be used to help identify SMP products potentially mixed with starches and starch degradation products and signal the need for more thorough analysis or investigation of the supply chain. This is not a pass/fail test, but rather a tool for users who are concerned and wish to monitor the presence and levels of starch and starch degradation products in their SMP ingredients. This work represents a great deal of effort by USP laboratories and meets an expressed need of our SMP Expert Panel.

General chapters

Horacio Pappa, Ph.D.
Director, General Chapters

I'm most proud of my group's work in the development of the *Stimuli* article on continuous manufacturing titled, "USP (Pharmacopeial) Perspective for Pharmaceutical Continuous Manufacturing," to be published in *PF* 44(6). The work this group has done will open the door for USP to a new arena. It will create opportunities for us to work on standardization of materials and processes that may facilitate the implementation of this new technology in the pharmaceutical industry. The article will also help to collect information from stakeholders to identify the specific areas that need further standardization and where USP can play an important role in the future."

General chapters provide specifications on tests, procedures, and other standards, as well as general guidance for *USP–NF* monographs. Expert Volunteers serve on six General Chapters ECs and the affiliated Expert Panels and subcommittees. The six ECs focus on chemical analysis, dosage forms, microbiology, packaging and distribution, physical analysis, and statistics. Their work impacts the quality control, packaging and supply integrity of drugs, as well as method validation and verification.

FY 18 Key Activities & Accomplishments

Continuous Manufacturing: The multi-disciplinary Quality Standards for Pharmaceutical Continuous Manufacturing Expert Panel has developed a *Stimuli* article on the impact that continuous manufacturing will have on the future of drug product manufacturing, the existing regulatory framework and regulatory expectations for continuous manufacturing, in accordance with Resolution I, which calls for collaboration with the FDA. The article also attempts to help standardize the definitions and terms used in pharmaceutical continuous manufacturing and outlines how risk management in pharmaceutical continuous manufacturing differs from batch manufacturing, in accordance with Resolution III, on globally harmonized standards.

Instrumentation: A *Stimuli* article was developed by members of the General Chapters–Physical Analysis Solutions Subcommittee and published in *PF* 44(4) [Jul.–Aug. 2018]. It proposes adding an instrumental method of color determination to General Chapter <631> *Color and Achromicity* to reflect available new technologies. The *Stimuli* article is a step toward modernizing visual appearance assessments by using quantitative instrumental methods, in accordance with Resolution II, on *USP–NF* monograph modernization.

Light-Scattering Chapters: General Chapter <1430> *Analytical Methodologies Based on Scattering Phenomena—General* and an associated family of five new chapters about analytical methodologies based on light scattering phenomena were published in *PF* 44(4). Once published in *USP–NF,* they will be the first general chapters to cover these techniques, which are widely used in industry for the development and control of critical product attributes. The general chapters also explain how to use these analytical methodologies appropriately for pharmacopeial testing, such as elucidating properties of proteins and other polymers in solution, in accordance with Resolutions II, on monograph modernization, V, on research and innovation within USP, and VI, on standards for biological medicines.

Analytical Procedure Lifecycle: The Validation and Verification Expert Panel of the General Chapters–Chemical Analysis EC has made progress in developing a lifecycle approach to analytical procedures and providing training and assistance to industry, as per Resolutions I and II. This work includes drafting examples and case studies in response to comments received.

New Chapter on Statistical Tools: The General Chapters Statistics EC has developed a new chapter detailing the statistical tools that are to be used in procedure validation, in accordance with Resolution V. General Chapter <1210> *Statistical Tools for Procedure Validation* is a companion to General Chapter <1225> *Validation of Compendial Procedures,* which discusses aspects to consider before validations, as well as how to establish analytical performance characteristics of accuracy, precision, and limit of detection.

Workshops: The General Chapters Group is continuing to explore the integration of new, tested technologies into the drafting and revision of standards. To help meet this goal, workshops are held that foster an environment conducive to the examination of innovative ideas. One such workshop was Computer Modeling—In Vitro and In Vivo Studies, held October 23–25, 2017, at USP–US, Rockville. This workshop allowed regulators, industry, and academia to discuss the use of computer modeling and simulation to accelerate product development and reduce costs, in accordance with Resolutions I, II, and V.

Pharmaceutical Water: *USP,* as the coordinating pharmacopeia, successfully obtained harmonization on the conductivity specification for Sterile Water for Injection. Discussion with the PDG and industry stakeholders is ongoing to replace the Oxidizable Substances test in the four sterile water monographs with a Total Organic Carbon test, in accordance with Resolutions II and III.

FY 18 Highlights: General Chapters

- 15 New General Chapters
- 12 Major Revisions of General Chapters
- 13 Regular Revisions of General Chapters
- 5 *Stimuli* Articles
- 4 New Monographs
- 23 Reference Standards Ballots

Healthcare & Quality Safety

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

FY 18 Key Activities & Accomplishments

Labeling: The revision of General Chapter <7> *Labeling* was published in *PF* 44(1) [Jan.-Feb. 2018]. After review of the public comments, the NL EC balloted to approve the revision and anticipates that the general chapter will become official on May 1, 2019.

Drug Allergies: The Drug Allergy and Intolerance Classification Expert Panel worked on a classification scheme to reduce preventable medication errors associated with patients' allergies and intolerance to medications.

USP Drug Classification: The USP Drug Classification Expert Panel identified refinements to the second version of the USP Drug Classification (USP DC 2019), which will be published for public comment in September 2018.

Opioids: In FY 18, the Opioid and Naloxone Subcommittee worked closely with stakeholders through roundtables and discussion forums to identify standards that may help improve patient safety with the therapeutic use of opioids and naloxone. The subcommittee is further developing storage and disposal standards and counseling standards for reducing opioid abuse.

Compounding: The Compounding EC published a major revision to General Chapter <795> *Pharmaceutical Compounding—Nonsterile Preparation* for public comment. After significant stakeholder engagement and collaboration through roundtables, discussion forums, and the addition of Expert Consultants to the Compounding EC, a revised proposal for General Chapter <797> *Pharmaceutical Compounding—Sterile Preparations* was published for a second round of public comments. USP also published a new General Chapter <1168> *Compounding for Phase I Investigational Studies*.

Handling Hazardous Drugs: USP announced the postponement of implementation of General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings* to align with the official date of the revised General Chapters <795> and <797>.

Patient Safety. More than 150 experts from around the world attended USP's inaugural Workshop on the Evolution and Advances in Compounding on May 21–22, 2018, at USP–US, Rockville, for discussions on the quality of compounding to improve patient safety through standardization of compounded medicines.

"In FY 18, USP launched the Compounded Preparation Monograph Donation Program to support ongoing work on developing monographs for compounded preparations. The Compounding Expert Committee developed 20 monographs and received more than 10 donations this year. USP also launched the <800> HazRx Mobile App. This app helps healthcare workers identify if the drug being handled is hazardous and provides guidance to help reduce their risk based on established standards such as General Chapter <800> and NIOSH guidance. USP continues to offer live and virtual compounding-related courses and has trained more than 2,000 students."

Jeanne Sun, Pharm.D.
Manager, Compounding Science – Healthcare Quality and Safety

FY 18 Highlights: Healthcare Quality & Safety

- 1 New Compounding Chapter
- 35 Drug Substance Titles
- 5 Compounded Preparation Titles

- 60 Drug Product Monograph Titles
- 22 Dietary Supplement Monograph Titles
- 7 Excipient Monograph Titles
- 12 Compounded Preparation Monographs

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Tejal Patel, EP

Guido Pauli, EC, JS3

Justin Pennington, EC

Ginette Pepper, EC, EP

Kent Peterson, EP

Matthew Pfefferkorn, EP

Julie Pier, EC, EP

David Pipes, EP

Stacey Platzer, EP

Luisa Fernanda Ponce De Leon, EP

James Ponto, EC, EP (2)

Guirag Poochikian, EC

Bert Popping, EC, EP, JS3

Reto Portmann, EP

Jean-Marc Poudrel, EC

Tammy Powell, EP

Seth Powsner, EP (3)

Lee Poye, EP

Nicole Provost, EC

Robert Przygoda, EP

Chetan Pujara, EC, EP

Anisul Quadir, EC

Oscar Quattrocchi, EC, EP (3), JS3

Nausheen Rahman, EP

Natarajan Rajagopalan, EP

Sundaram Ramachandran, EP

Karthik Ramani, EP

Vijaya Ramesh, EC

William Randolph, EP

Sam Raney, EP

Pradyumna Rao, EP

Rao Rapaka, EP

Neil Ravenscroft, EP

Elizabeth Read, EC, EP

Shahnaz Read, EC, EP

David Reed, EC

Eike Reich, EC

Cindy Reid, EC

Lars Reimann, EP, JS3

Thomas Reinders, EC, EP

Gurvinder Singh Rekhi, EC

Volker Rekowski, EP

James Rice, EC, EP, JS3

Peter J. Rice, EC, EP, JS3

Sarah Richer, EP

Steven Richter, EP

Cynthia Rider, EP

Anthony Ridgway, EC

Peter Rigsby, EC

Dean Ripple, EP

Jennifer Roark, EP

George Robinson, EP

Helmut Rockstroh, EC, EP

Harold Rode, EC, EP, JS3

Jason Rodriguez, EP

Amy Roe, EC, EP (2), JS3

Holger Roehl, EP

David Roesti, EC, EP

David Rogers, EC, EP

Jeff Rohrer, EC, EP

Agusti Jordi Romero, EP

Thomas Rosanske, EC

William Rosenthal, EP

Bruno Rossi, EP

Abby Roth, EC

Sara Rothman, EP

Michael Ruberto, EP

Raimon Rubires, EC

Gwen Rucker, EC, EP

N. Lee Rucker, EC, EP

Andrew Rugaiganisa, EP

Marcia Rusjan, EP

Martin Rutstein, EP

Melody Ryan, EC

Jack Saad, EP

Shobhan Sabnis, EC

Gordon Sacks, EP

Wendy Saffell-Clemmer, EC

Iffaaz Salahudeen, EC, JS3

Matthew Sanchez, EP

Dennis Sandell, EC, EP

Mary Ellen Sanders, EP

Maria Ines Santoro, EC, JS3

Camilla Santos, EP

Murugan Saravanan, EC

R.D. Satzger, EP

Zuben Sauna, EP

Anita Sawyer, EP

Maureen Schanck, EP

Silke Schepelmann, EP

Paul Schiff, EC

Jennifer Schimmel, EC

Jean Schoeni, EP

Timothy Schofield, EC, EP

David Schuck, EC

Joanne Schwartzberg, EC (2), EP

Jeff Schwartzenhauer, EC

Stephan Schwarzinger, EP

Mark Schweitzer, EC, EP (2)

Myke Scoggins, EC

Robert Seevers, EC

Alan Segrave, EP

Mary Seibel, EC, EP

Donna Seibert, EC

Mauricio Seigelchifer, EC, EP

David Seres, EP

Barbara Serr, EC

John Shabushnig, EC, EP

Maged Sharaf, EC

Hemant Kumar Sharma, EC, EP

Vaneet Sharma, EC, EP

Steven Shaw, EP

Eric Sheinin, EC

Rakesh Shekhawat, EP

Timothy Shelbourn, EC, EP

Shangmei Shi, EC, EP

Hiroko Shibata, EP

Judy Shimoni, EP

Deborah Shnek, EP

Ed Shneyvas, EP

Robert Shrewsbury, EC

Roger Simonds, EP

Donald Singer, CoE, EC, EP, JS3

Robert Singer, CoE, EC, EP, JS3

Hameraj Singh, EC, EP (2), JS3

Satish Singh, EC, EP (2), JS3

Michael Skibic, EC

Raymond Skwierczynski, EC, EP (2)

Rostyslaw Slabicky, EC, EP (2)

Patricia Sokol, EC, EP

Teri Soli, EC, EP (2)

Brian Solow, EP

Aniko Solyom, EC

Perceval Sondag, EP

Haowei Song, EP

John Spink, EP, JS3

Shelly Spiro, EP

Jan Srbek, EC

Charudharshini Srinivasan, EP

Jannavi Srinivasan, EP

Ved Srivastava, EC

Buffy Stahl, EP

Nomi Steen, EP

Ralf Stegmann, EP

Robert Steininger, EP

Dennis Stephens, EC

Andy Stergachis, EP

Jonathan Stewart, EC

Paul Stinavage, EC

Ann Stohlman, EP

Joseph Stowell, EC

Seth Strawbridge, EP

Greg Strossman, EP

Cheryl Stults, EC, EP (2)

Jason Suggett, EC, EP

Karunakar Sukuru, EC

Connie Sullivan, EC, EP

Darryl Sullivan, EC, EP

Changquan Sun, EC, EP

Huimin Sun, EC, EP

Zhigang Sun, EC, EP

Teresa Surowy, EP

Colleen Sutton, EP

Kelly Swinney, EP

Jennifer Swisher, EP

Kevin Swiss, EC, EP (3)

Ami Fazlin Syed Mohamed, EP

Christina Szabo, EC

Neeru Takiar, EP (3)

Philippe Talaga, EP

Charles Tan, EC

Neeraj Tandon, EP

Thomas Tarantelli, EP, JS3

William Taraszewski, EC

Carmen Tartera, EP

J. Russell Teagarden, EC, EP (2)

Max Tejada, EP

Monica Tejwani, EC, EP (2)

Allen Templeton, EC, EP

Kailas Thakker, EP

David Thomas, EP

Jennifer Thomas, EP

Rene Thuermer, EP

Thomas Tice, EC (2), EP

Edward Tidswell, EC, EP

Stephen Tindal, EP (2)

Gary Tomaino, EP

Jacqueline Tordik, EC

Viet Hung Tran, EP

Giordano Trazzi, EC

Keith Trettin, EP

Bernhardt Trout, EP

Yiying Tsai, EP

Jiasheng Tu, EC, EP

Jeanne Tuttle, EC, EP

Yoko Uematsu, EC, EP, JS3

Katherine Ulman, EP

Patrick Vallano, EP

Edwin van den Heuvel, EC

Mark van Ooij, EP

Drew Van Orden, EP

Peter Vandeberg, EC

Maureen Vander Fliet, EP

Christina Vegge, EP

Michael Verlander, EC, EP

Charles Vesey, EC

Kathy Vieson, EP

Ofelia Villalva-Rojas, EP

Claudia Vincenzi, EC

Luciano Virgili, EC

Christian Viskov, EC, EP

Gordon Vrdoljak, EP

Madhusudan Vudathala, EP

James Wagner, EC

Amy Walia, EP

Michael Walsh, EP

Reinhard Walter, CoE, EC

Hailin Wang, EC, EP

Hu Wang, EC, EP

Selina Wang, EC, EP

Weihong Wang, EC, EP

Xiaoping Wang, EC, EP

Yuwen Wang, EC, EP

Zhenyu Wang, EC, EP

Terri Warholak, EC

Kevin Warner, EC

Kara Weatherman, EP

James Webber, EP

Darin Weber, EC

Vera Weinstein, EP

Caroline R. Weinstein-Oppenheimer, EP

William Weiss, EP

Jane Weitzel, EC, EP, JS3

Eloise Welfare, EC, EP

Richard Wendt, EC, JS3

Eric Wenger, EP

Dennis West, EP

Kylen Whitaker, EC

Zeena Williams, EC

Martin Williamson, EC, EP, JS3

Benjamin Wilson, EP

Carl Winter, EP, JS3

Allison Wolf, EP

Steve Wolfgang, EP (2)

Ken Wong, EP

Surapote Wongyai, EP

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Gillian Woollett, EC

Wesley Workman, CoE, EC, EP, JS3

Pat Worthington, EP

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Chao Wu, EC, EP, JS3

Di Wu, EC, EP, JS3

Fan Wu, EC, EP, JS3

Larisa Wu, EC, EP, JS3

Wanying Wu, EC, EP, JS3

Yongning Wu, EC, EP, JS3

Dale Wurster, EC

Joshua Wurzer, EP

Min Xia, EC

Li Xiong, EC

Renliang Xu, EP

Sam Yaghmour, EP

Betsy Yakes, EP

Joseph Yakupkovic, EC

Ryan Yamagata, EP

Teruhide Yamaguchi, EC

Bing-Shiou Yang, EC, EP

Harry Yang, EC, EP

Jinchuan Yang, EC, EP

Jingyue Yang, EC, EP

Timothy Yasika, EC

Patrick Yat, EC

Mehran Yazdanian, EC

Hsiang Shonna Yin, EC, EP

Lisa Yoest, EP

Gao Yonghua, EC, EP

Stephen Young, EP

Liangli Yu, EC

Yaozuo Yuan, EC

Brenda Yuzdepski, EC

Earl Zablackis, EC, EP (4)

Lingmin Zeng, EP

Geoff Zhang, EC, EP

Jin Zhang, EC, EP

Ying Zhang, EC, EP

Yongqiang Zhang, EC, EP

Jin Zhao, EC, EP

Zhongzhen Zhao, EC, EP

Hong Zhou, EP

Wei Zhu, EP

Steve Zigler, EC, EP (3)

Yuda Zong, EP

Anthony Zook, EP

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