Appeal of Revisions to General Chapters <797> and <795>

January 22, 2020

United States Pharmacopeia

12601 Twinbrook Pkwy., Rockville, MD 20852

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Table of Contents: Topics to Be Covered During Today's Appeal Hearing

Introduction

The Coalition: Why We Are Here

- **Alliance for Pharmacy Compounding**
  Scott Brunner (CEO)
  Jennifer Burch (Chair, Executive Committee)
  Erik Tosh (Vice President, Compounding Support Services)

Alliance for Pharmacy Compounding

- **Innovation Compounding**
  Shawn Hodges (President and CEO)

INNOVATION COMPOUNDING

- **Wedgewood Village Pharmacy**
  Barry Siegel (General Counsel)
  Anthony Grzib (Director of Pharmacy Compliance)

wedgewood PHARMACY

The Coalition: Why We Are Here

- The Coalition's members, either directly or through their member organizations, are deeply involved with the development or dissemination of compounded sterile preparations ("CSPs") or compounded nonsterile preparations ("CNSPs").
- The Coalition is concerned that its patients and/or other constituents will be severely and adversely affected by USP's worrisome and ill-considered revisions to USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations and to USP General Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations.
- Among other things, those revisions would shorten the beyond-use dates ("BUDs") assigned to CSPs or CNSPs which, in turn, will severely and negatively impact patient safety and care.
- The Coalition is appealing these changes and requesting that USP withdraw the proposed revisions to Chapters <795> and <797> and remand to a newly constituted Compounding Expert Committee ("CEC") to start fresh.

The Coalition: Why We Are Here

BUD Provisions Chapter <797>

Official <797> (last revised in 2008)	Revised <797> (published June 1, 2019)
Low-risk in segregated compounding area • 12 hours at CRT* Low-risk • 48 hours at CRT • 14 days in a refrigerator • 45 days in a freezer Medium-risk • 30 hours at CRT • 9 days in a refrigerator • 45 days in a freezer High-risk • 24 hours CRT • 3 days refrigerator • 45 days frozen	Category 1 • ≤ 12 hours at CRT • ≤ 24 hours in a refrigerator Category 2 • Aseptically processed, no sterility, only sterile starting components • 4 days at CRT • 10 days in a refrigerator • 45 days in a freezer • Aseptically processed, no sterility, one or more nonsterile starting component(s) • 1 day at CRT • 4 days in a refrigerator • 45 days in a freezer

- Chapter <797> previously assigned BUDs based on two factors: (i) a CSP's nonsterility risk factor and (ii) its storage conditions.
- But now, under the revision, BUD assignment is based on five factors: (i) whether a CSP falls into "Category 1" or "Category 2"; (ii) whether it was aseptically processed or terminally sterilized; (iii) whether it was sterility tested; (iv) whether it was prepared from a sterile or nonsterile starting component; and (v) its storage conditions.
- **Thus, under this new system, all CSPs, regardless of the conditions under which they are prepared, are presumed to have a high risk of nonsterility, and will therefore have drastically shorter BUDs**; that, in turn, will force compounders to make smaller batch sizes, thereby increasing costs and effectively preventing many compounds from being made.
- In this respect, the Coalition determined that an estimated 91% of the CSPs it or its member organizations compound will be assigned shorter BUDs under the new regime—with the average BUD for certain categories of CSPs being shortened by ***five months***.

The Coalition: Why We Are Here

BUD Provisions Chapter <795>

Official <795> (last revised in 2014)	Revised <795> (published June 1, 2019)
Water containing oral formulations = **14 days**	Non-preserved aqueous = **14 days**
Water-containing topical/dermal and mucosal liquids and semisolid = **30 days**	Preserved aqueous = **35 days**
Nonaqueous formulations = **6 months**	Nonaqueous dosage forms = **90 days**
	Solid dosage forms = **180 days**

- One type of formulation that has been impacted by the new BUD table is fixed oil suspensions, which previously had a **180 day BUD**. In the revised chapter, fixed oil suspensions have a **90 day BUD**.

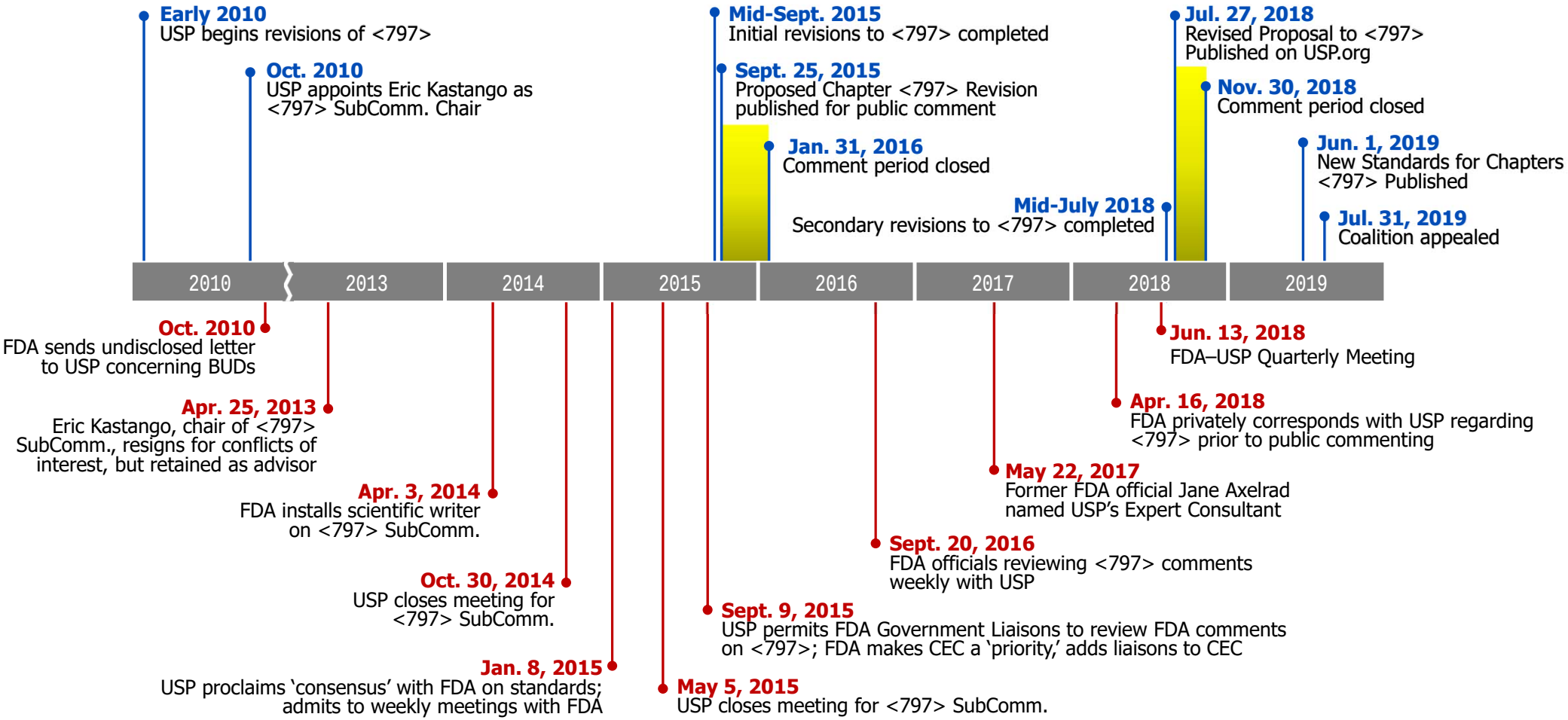
- The practical effect of this BUD reduction is twofold: i) compounders will be forced to produce smaller CNSP batches more often to meet patient needs, **increasing the cost** to make each unit; and ii) compounders **will not be able to make adequate amounts** of CNSPs far enough in advance of receiving prescriptions to meet patient needs.

The Coalition: Why We Are Here

- The Coalition appealed the revisions to Chapters <797> and <795>.
- The Coalition's appeal raised four main substantive concerns:

1. Shortened BUDs are not based on science and conflict with scientifically sound information found elsewhere in USP's standards.
2. The rationale for the revised BUDs is based on the premise that the previous Chapter <797> standards could not provide adequate assurance of sterility, thereby calling into question the value of the entire chapter.
3. Shortened BUDs will have a profoundly negative impact on patient safety due to a lack of availability of compounded pharmaceuticals and/or treatment interruptions.
4. Compounders will now face tremendous difficulties in trying to comply with the onerous, unprecedented demands imposed by the new standards, including by forcing them to produce smaller CSP and CNSP batches at a much higher cost.

The Coalition: How We Got Here



The Coalition's Concerns

Roadmap of the Coalition's Appeal

1. **Threshold Legal Concerns**
2. **Problems with USP's Development of the Revised Chapters**
3. **Problems with the Adequacy of this Appeal Hearing**
4. **Remand to New, Fairly Informed CEC**

Roadmap of the Coalition's Appeal

1. **Threshold Legal Concerns**
2. Problems with USP's Development of the Revised Chapters
3. Problems with the Adequacy of this Appeal Hearing
4. Remand to New, Fairly Informed CEC

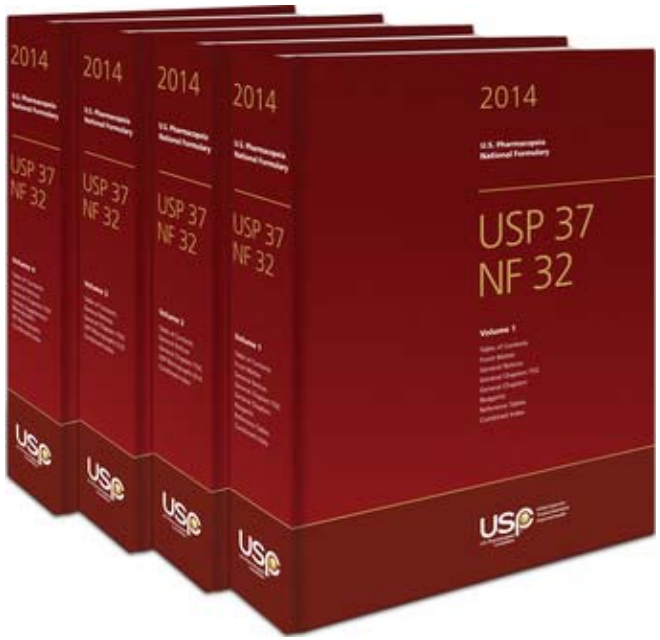
USP's Unique Status Under Federal Law

- USP is a ***private***, ***non-governmental organization*** that, among other things, revises and drafts compendial standards, including the official USP-NF compendium.
- The idea for USP developed in early colonial America, as physicians and apothecaries largely relied on pharmacopeias published in London and Edinburgh for guidance.
- In 1818, Dr. Lyman Spalding invited medical societies and schools to send delegates to regional conferences, where delegates would draft versions of a pharmacopeia for submission to a national conference.

USP's Unique Status Under Federal Law

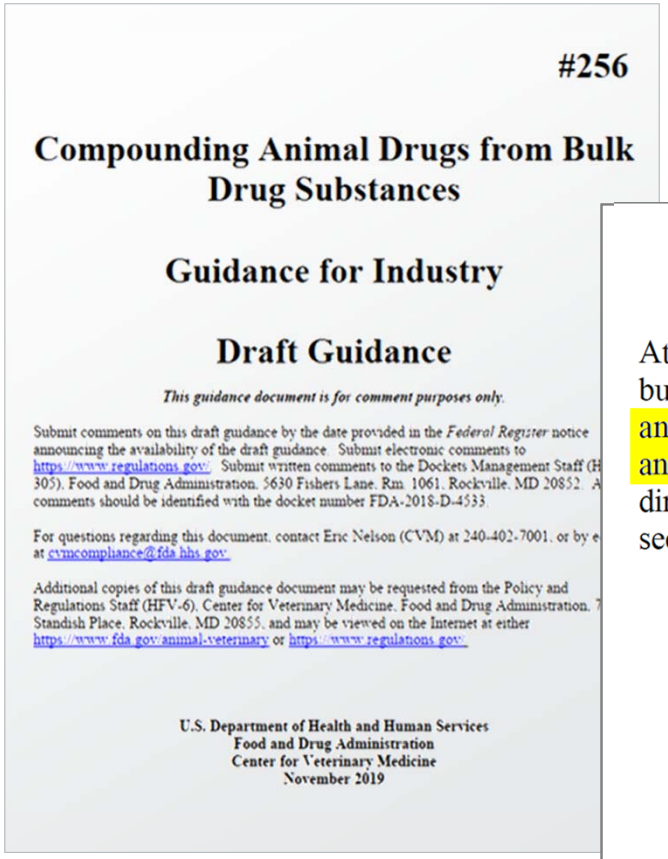
- The first USP standards were published in December 1820.
- The USP standardized the ways in which patients obtained and used pharmaceuticals.
- The USP standards continued to be revised and republished every 10 years.
- By the early 1900s, the USP standards gained wide acceptance in the drug trade as an authoritative reference work.
- The USP standards were incorporated into federal law in 1906 in the Pure Food and Drug Act, and subsequently amended in 1937 by the Food, Drug, and Cosmetic Act ("FDCA").

USP Standards Incorporated into Federal Law



- FDCA provides that when a drug is recognized by the USP, "it shall be subject to the requirements of the United States Pharmacopeia." 21 U.S.C. § 351(b).
- FDCA incorporates all future revisions to USP's standards. 21 U.S.C. § 351(b).
- FDCA defines drug "adulteration" by reference to USP standards. 21 U.S.C. § 351(b).
- FDCA defines when a drug is "misbranded" by reference to USP standards. 21 U.S.C. §502(g).
- Because FDCA's definition of "drug" incorporates USP standards, it enables the USP to fundamentally alter what items qualify as drugs under federal law.

USP Standards Incorporated into Federal Law



#256

Compounding Animal Drugs from Bulk Drug Substances

Guidance for Industry

Draft Guidance

This guidance document is for comment purposes only.

Submit comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (H 305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A comments should be identified with the docket number FDA-2018-D-4533.

For questions regarding this document, contact Eric Nelson (CVM) at 240-402-7001, or by e at cvmcompliance@fda.hhs.gov.

Additional copies of this draft guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either https://www.fda.gov/animal-veterinary or https://www.regulations.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
November 2019

- Recently issued FDA Guidance expressly recognizes that failure to adhere to USP standards could lead to criminal prosecution:

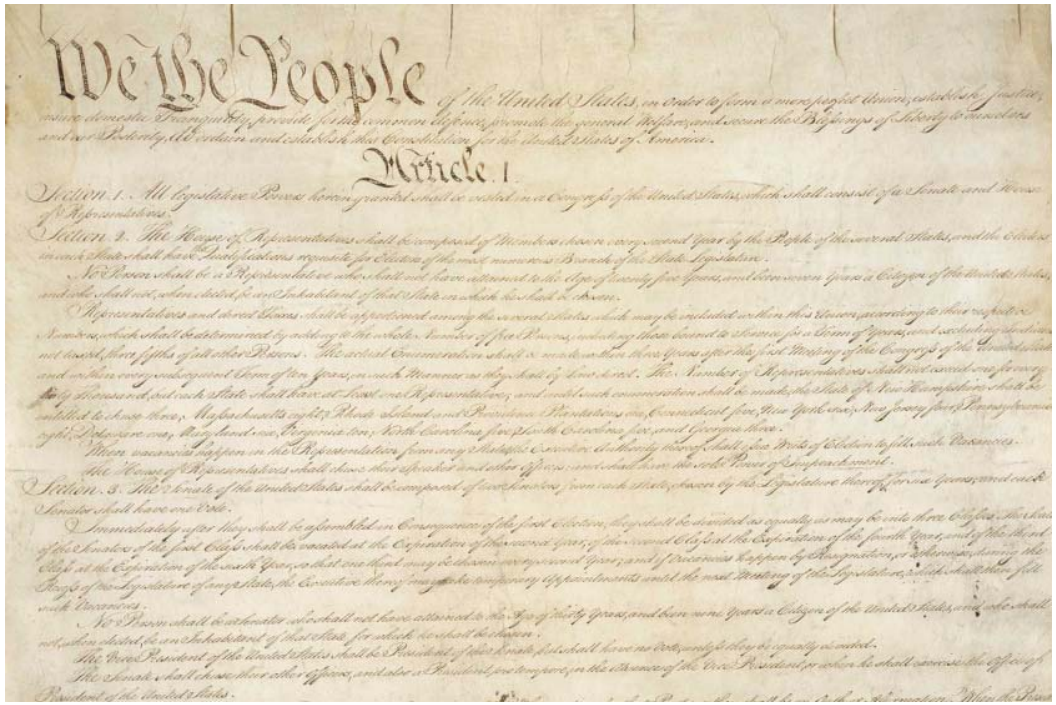
A. Compounding Pursuant to Patient-Specific Prescriptions for Nonfood-Producing Animals

At this time and based on our current understanding of the risks of animal drugs compounded from bulk drug substances, FDA does not intend to take enforcement action against the compounding of animal drugs from bulk drug substances for any nonfood-producing animal for violations of the new animal drug approval requirements in sections 512 and 501(a)(5) of the FD&C Act, the adequate directions for use requirements in section 502(f)(1) of the FD&C Act, and the cGMP requirements in section 501(a)(2)(B) of the FD&C Act, provided:

1. The drug is compounded by or under the direct supervision of a veterinarian or a pharmacist in a State-licensed pharmacy or Federal facility;
2. The drug is compounded in accordance with the current United States Pharmacopeia and National Formulary (USP-NF) Chapters <795> "Pharmaceutical Compounding – Nonsterile Preparations" or <797> "Pharmaceutical Compounding-Sterile Preparations" and complies with the standards of all applicable USP-NF monographs (*e.g.*, a monograph for a bulk drug substance or a monograph for a compounded finished product);

Source Document: Compounding Animal Drugs from Bulk Drug Substances, U.S. Food & Drug Admin., Guidance for Industry, Draft Guidance, No. 256, dated Nov. 2019.

The Problem? USP's Incorporation into Federal Law Is *Unconstitutional*



- Article I, Section I of the U.S. Constitution provides that "[***a***]***ll legislative Powers herein granted shall be vested in a Congress of the United States***[.]" U.S. CONST. art. 1, § 1.
- From Article I, Section I of the U.S. Constitution comes the ***non-delegation doctrine***, which prevents Congress from farming its legislative power out to anyone outside of the Legislature.

The Non-Delegation Doctrine and Separation of Powers

Cite as: 516 U. S. 264 (1996) 279

Opinion of SCALIA, J.

however, that best sets forth the reasons for reversing the judgment of the Court of Appeals.

JUSTICE BREYER has authorized me to say that he agrees with the foregoing views.

JUSTICE SCALIA, concurring in part and concurring in the judgment.

I agree with the Court's opinion, except that portion of it which enters into a discussion of "[t]he drafting history of § 4010." *Ante*, at 273. In my view a law means what its text most appropriately conveys, whatever the Congress that enacted it might have "intended." The law *is* what the law *says*, and we should content ourselves with reading it rather than psychoanalyzing those who enacted it. See *United States* v. *Public Util. Comm'n of Cal.*, 345 U. S. 295, 319 (1953) (Jackson, J., concurring). Moreover, even if subjective intent rather than textually expressed intent were the touchstone, it is a fiction of Jack-and-the-Beanstalk proportions to assume that more than a handful

Senators and Members of the House who voted fo

version of the Expedited Funds Availability Act

President who signed it, were, when they took thos

aware of the drafting evolution that the Court desc

if they were, that their actions in voting for or si

final bill show that they had the same "intent" w

evolution suggests was in the minds of the drafter

JUSTICE STEVENS acknowledges that this is so, b

that the intent of a few committee members is n

dispositive because legislators are "busy people,"

Members [of Congress] are content to endorse the

the responsible committees." *Ante*, at 276. I do

the factual basis for that assurance. Many con

committees tend not to be representative of the fu

but are disproportionately populated by Membe

constituents have a particular stake in the subject

agriculture, merchant marine and fisheries, science

nology, etc. I think it quite unlikely that the Hous

264 OCTOBER TERM, 1995

Syllabus

BANK ONE CHICAGO, N. A. *v.* MIDWEST BANK & TRUST CO.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

No. 94–1175. Argued November 28, 1995—Decided January 17, 1996

the Constitution forbids it. Article I, § 1, provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and a House of Representatives." It has always been assumed that these powers are nondelegable—or, as John Locke put it, that legislative power consists of the power "to make laws, . . . not to make legislators." J. Locke, Second Treatise of Government 87 (R. Cox ed. 1982). No one would

Source Document: *Bank One Chicago, N.A. v. Midwest Bank & Tr. Co.*, 516 U.S. 264, 280 (1996) (Scalia, J., concurring in pat and concurring in the judgment).

The Non-Delegation Doctrine and the "Intelligible Principle"

472 WHITMAN *v.* AMERICAN TRUCKING ASSNS., INC.

Opinion of the Court

III

Section 109(b)(1) of the CAA instructs the EPA to set "ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on [the] criteria [documents of § 108] and allowing an adequate margin of safety, are requisite to protect the public health." 42 U. S. C. § 7409(b)(1). The Court of Appeals held that this section as interpreted by the Administrator did not provide an "intelligible principle" to guide the EPA's exercise of authority in setting NAAQS. "[The] EPA," it said, "lack[ed] any determinate criteria for drawing lines. It has failed to state intelligibly how much is too much." 175 F. 3d, at 1034. The court hence found that the EPA's interpretation (but not the statute itself) violated the nondelegation doctrine. *Id.*, at 1038. We disagree.

In a delegation challenge, the constitutional question is whether the statute has delegated legislative power to the agency. Article I, § 1, of the Constitution vests "[a]ll legislative Powers herein granted . . . in a Congress of the United States." This text permits no delegation of those powers. *Loving* v. *United States*, 517 U. S. 748, 771 (1996); s
776–777 (SCALIA, J., concurring in part and c
in judgment), and so we repeatedly have said t
Congress confers decisionmaking authority upon
Congress must "lay down by legislative act an i
principle to which the person or body authorized
directed to conform." *J. W. Hampton, Jr., & Co.*
States, 276 U. S. 394, 409 (1928). We have never s
that an agency can cure an unlawful delegation of l
power by adopting in its discretion a limiting const
the statute. Both *Fahey* v. *Mallonee*, 332 U. S. 245
(1947), and *Lichter* v. *United States*, 334 U. S. 742, 7
mention agency regulations in the course of their n
tion discussions, but *Lichter* did so because a su
Congress had incorporated the regulations into
version of the statute, *ibid.*, and *Fahey* because th

OCTOBER TERM, 2000 457

Syllabus

WHITMAN, ADMINISTRATOR OF ENVIRONMENTAL PROTECTION AGENCY, ET AL. *v.* AMERICAN TRUCKING ASSOCIATIONS, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 99–1257. Argued November 7, 2000—Decided February 27, 2001*

in judgment), and so we repeatedly have said that when Congress confers decisionmaking authority upon agencies *Congress* must "lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform." *J. W. Hampton, Jr., & Co.* v. *United States*, 276 U. S. 394, 409 (1928). We have never suggested

Source Document: *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 472 (2001).

Delegation to USP *Per Se* Unconstitutional?

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued February 19, 2013 Decided July 2, 2013

No. 12-5204

ASSOCIATION OF AMERICAN RAILROADS,
APPELLANT

v.

UNITED STATES DEPARTMENT OF TRANSPORTATION, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:11-cv-01499)

Thomas H. Dupree, Jr. argued the cause for appellant. With him on the briefs was *Louis P. Warchot.*

Michael S. Raab, Attorney, U.S. Department of Justice, argued the cause for appellees. With him on the brief were *Stuart F. Delery*, Acting Assistant Attorney General, *Ronald C. Machen Jr.*, U.S. Attorney, *Mark B. Stern* and *Daniel Tenny*, Attorneys, *Paul M. Geier*, Assistant General Counsel for Litigation, U.S. Department of Transportation, *Peter J. Plocki*, Deputy Assistant General Counsel for Litigation, and *Joy Park*, Attorney.

1095, 1143 (D.C. Cir. 1984) (per curiam).[3] Even an intelligible principle cannot rescue a statute empowering private parties to wield regulatory authority. Such entities may, however, help a government agency make its regulatory decisions, for "[t]he Constitution has never been regarded as denying to the Congress the necessary resources of flexibility and practicality" that such schemes facilitate. *Pan. Ref. Co. v. Ryan*, 293 U.S. 388, 421 (1935). Yet precisely how much involvement may a private entity have in the administrative process

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Sunshine Anthracite Coal Co. v. Adkins, 310 U.S. 381 (1940). In *Currin* Congress circumscribed its delegations of

[3] At least one commentator has suggested that the "doctrine forbidding delegation of public power to private groups is, in fact, rooted in a prohibition against self-interested regulation that sounds more in the Due Process Clause than in the separation of powers." A. Michael Froomkin, *Wrong Turn in Cyberspace: Using ICANN To Route Around the APA and the Constitution*, 50 DUKE L.J. 17, 153 (2000). *Carter Coal* offers some textual support for this position, describing the impermissible delegation there as "clearly a denial of rights safeguarded by the due process clause of the Fifth Amendment." 298 U.S. at 311. While the distinction evokes scholarly interest, neither party before us makes this point, and our own precedent describes the problem as one of unconstitutional delegation. *See NARUC*, 737 F.2d at 1143 n.41. And, in any event, neither court nor scholar has suggested a change in the label would effect a change in the inquiry.

1095, 1143 (D.C. Cir. 1984) (per curiam).[3] Even an intelligible principle cannot rescue a statute empowering private parties to wield regulatory authority. Such entities

Source Document: *Ass'n of Am. Railroads v. U.S. Dep't of Transp.*, 721 F.3d 666, 668 (D.C. Cir. 2013), *vacated and remanded sub nom. Dep't of Transp. v. Ass'n of Am. Railroads*, 135 S. Ct. 1225 (2015).

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7

A

We open our discussion with a principle upon which both sides agree: Federal lawmakers cannot delegate regulatory authority to a private entity. To do so would be "legislative delegation in its most obnoxious form." *Carter v. Carter Coal Co.*, 298 U.S. 238, 311 (1936). This constitutional prohibition is the
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agency is for Congress to prescribe an intelligible principle governing the statute's enforcement. *See J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928).

Not so, however, in the case of private entities to whom the Constitution commits no executive power. Although objections to delegations are "typically presented in the context of a transfer of legislative authority from the Congress to agencies," we have reaffirmed that "the difficulties sparked by such allocations are even more prevalent in the context of agency delegations to private individuals." *Nat'l Ass'n of Regulatory Util. Comm'rs v. FCC* ("*NARUC*"), 737 F.2d

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The Non-Delegation Doctrine and the "Intelligible Principle"

- When Congress wants to provide statutory authorization for an agency within the Executive Branch to regulate, Congress is constitutionally constrained to do so pursuant to an "***intelligible principle***"—that is, a ***clear prescription for how its delegated authority is to be used***. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 472 (2001) (emphasis added).

- When Congress fails to provide any "***guidance for the exercise of discretion***," it has failed to offer an "intelligible principle," and any attempted delegation of legislative authority, even within the federal government, is unconstitutional. *Id.* at 474 (emphasis added).

No "Intelligible Principle" Constrains USP

- FDCA's sweeping delegation of power to the USP is not accompanied by ***any*** statutory language to guide or constrain its conduct.
- FDCA does not allow FDA (or any other governmental entity) to ***modify or veto*** additions or revisions to the USP.
- Any additional articles added to the USP standards are ***automatically incorporated*** in the definition of "drug," and any changes to drug standards are automatically incorporated into law.

Non-Delegation Doctrine: *Not if…but when…*

JURISPRUDENCE

The Supreme Court's Conservatives Are Ready to Take a Wrecking Ball to the Entire Federal Bureaucracy

By MARK JOSEPH STERN JUNE 20, 2019 • 5:59 PM

Supreme Court Justices Samuel Alito and Neil Gorsuch.
Photo illustration by Slate. Photos by Chip Somodevilla/Getty Images and Jabin Botsford—Pool/Getty Images.

The Supreme Court declined to upend the administrative state on Thursday in a split decision that augurs coming earthquakes in constitutional law. Think executive agencies have too much power to interpret and enforce the law? Want courts to dismantle landmark statutes protecting the environment, consumers, and employees? You may be in luck: The conservative justices are eager to take a hatchet to the federal bureaucracy that governs much of modern

REPUBLICAN-APPOINTEES TO THE U.S. SUPREME COURT

- A majority of Supreme Court Justices have signaled an inclination to enforce the non-delegation doctrine.

Source Document: Mark Stern, *The Supreme Court's Conservatives Are Ready to Take a Wrecking Ball to the Entire Federal Bureaucracy*, Slate (June 20, 2019).

Non-Delegation Doctrine: *Not if…but when…*

Cite as: 588 U. S. ____ (2019) 1

GORSUCH, J., dissenting

SUPREME COURT OF THE UNITED STATES

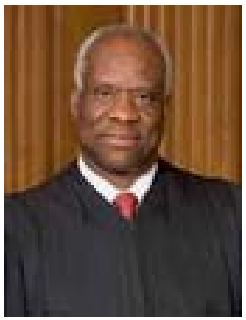
No. 17–6086

HERMAN AVERY GUNDY, PETITIONER *v.*
UNITED STATES

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

[June 20, 2019]

JUSTICE GORSUCH, with whom THE CHIEF JUSTICE and JUSTICE THOMAS join, dissenting.



8 GUNDY *v.* UNITED STATES

GORSUCH, J., dissenting

of the majority.[26] Restricting the task of legislating to one branch characterized by difficult and deliberative processes was also designed to prom
law, ensuring the people w
stable and predictable set o
legislating be done only b
public process, the Constitution sought to ensure that the lines of accountability would be clear: The sovereign people would know, without ambiguity, whom to hold accountable for the laws they would have to follow.[28]

JUSTICE GORSUCH, with whom THE CHIEF JUSTICE and JUSTICE THOMAS join, dissenting.

If Congress could pass off its legislative power to the executive branch, the "[v]esting [c]lauses, and indeed the entire structure of the Constitution," would "make no sense."[29] Without the involvement of representatives from

suffer too. Legislators might seek to take credit for addressing a pressing social problem by sending it to the executive for resolution, while at the same time blaming the executive for the problems that attend whatever measures he chooses to pursue. In turn, the executive might point to Congress as the source of the problem. These opportunities for finger-pointing might prove tempt-

[26] The Federalist No. 51, at 322. See also *id.*, No. 84, at 515 (Hamilton).
[27] *Id.*, No. 62, at 378–380.
[28] Schoenbrod 99; see also The Federalist No. 50, at 316 (Madison).
[29] Lawson, Delegation and Original Meaning, 88 Va. L. Rev. 327, 340 (2002).
[30] The Federalist No. 47, at 303 (Madison); *id.*, No. 62, at 378 (same).

Source Document: *Gundy v. United States*, 139 S. Ct. 2116, 2134 (2019) (Gorsuch, J., dissenting).

Non-Delegation Doctrine: *Not if…but when…*

Cite as: 588 U. S. ____ (2019) 1

GORSUCH, J., dissenting

SUPREME COURT OF THE UNITED STATES

No. 17–6086

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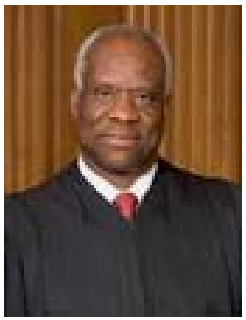


10 GUNDY *v.* UNITED STATES

GORSUCH, J., dissenting

B

Accepting, then, that we have an obligation to decide whether Congress has un
its legislative responsibili
the test? Madison ackr
science of government ha
and define, with sufficient certainty, its three great provinces—the legislative, executive, and judiciary."[34] Chief Justice Marshall agreed that policing the separation of

"those of less interest, in which a general provision may be made, and power given to those who are to act . . . to fill up the details."[36] The Court upheld the statute before it because Congress had announced the controlling general policy when it ordered federal courts to follow state procedures, and the residual authority to make "alterations and additions" did no more than permit courts to fill up the details.

Later cases built on Chief Justice Marshall's understanding. In *In re Kollock*, for example, the Court upheld

[34] *Id.*, No. 37, at 228 (Madison).
[35] *Wayman*, 10 Wheat., at 46.
[36] *Id.*, at 31, 43.

JUSTICE GORSUCH, with whom THE CHIEF JUSTICE and JUSTICE THOMAS join, dissenting.

Accepting, then, that we have an obligation to decide whether Congress has unconstitutionally divested itself of its legislative responsibilities, the question follows: What's the test? Madison acknowledged that "no skill in the

Source Document: *Gundy v. United States*, 139 S. Ct. 2116, 2134 (2019) (Gorsuch, J., dissenting).

Non-Delegation Doctrine: *Not if…but when…*

SUPREME COURT OF THE UNITED STATES

No. 17–6086

HERMAN AVERY GUNDY, PETITIONER *v.*
UNITED STATES

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

[June 20, 2019]

JUSTICE ALITO, concurring in the judgment.

The Constitution confers on Congress certain "legislative [p]owers," Art. I, §1, and does not permit Congress to delegate them to another branch of the Government. See *Whitman* v. *American Trucking Assns., Inc.*, 531 U. S. 457, 472 (2001). Nevertheless, since 1935, the Court has uniformly rejected nondelegation arguments and has upheld provisions that authorized agencies to adopt important rules pursuant to extraordinarily capacious standards. See *ibid.*

If a majority of this Court were willing to reconsider the approach we have taken for the past 84 years, I would support that effort. But because a majority is not willing to do that, it would be freakish to single out the provision at issue here for special treatment.

Because I cannot say that the statute lacks a discernable standard that is adequate under the approach this Court has taken for many years, I vote to affirm.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

[June 20, 2019]

JUSTICE ALITO, concurring in the judgment.

If a majority of this Court were willing to reconsider the approach we have taken for the past 84 years, I would support that effort. But because a majority is not willing

Non-Delegation Doctrine: *Not if…but when…*

Kavanaugh Joins Gorsuch in Fight To Revive Nondelegation Doctrine

An important development in the legal wrangling over the separation of powers.

DAMON ROOT | 11.25.2019 1:10 PM

The U.S. Supreme Court narrowly upheld a law in June that, in the dissenting words of Justice Neil Gorsuch, "ha… nation's chief prosecutor the power to write his own criminal code." Today, Justice Brett Kavanaugh spoke up in support of Gorsuch.

The June ruling came in *Gundy v. United States*, a case that centered on a 2006 federal law known as the Sex Offender Registration and Notification Act (SORNA). Among other things, SORNA required convicted sex offenders to register, check in periodically in

Cite as: 589 U. S. ____ (2019) 1

Statement of KAVANAUGH, J.

SUPREME COURT OF THE UNITED STATES

RONALD W. PAUL *v.* UNITED STATES

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

No. 17–8830. Decided November 25, 2019

The petition for a writ of certiorari is denied.

Statement of JUSTICE KAVANAUGH respecting the denial of certiorari.

I agree with the denial of certiorari because this case ultimately raises the same statutory interpretation issue that

built on views expressed by then-Justice Rehnquist some 40

U. S. ___ (2019). I write separately because JUSTICE GORSUCH's scholarly analysis of the Constitution's nondelegation doctrine in his *Gundy* dissent may warrant further consideration in future cases. JUSTICE GORSUCH's opinion

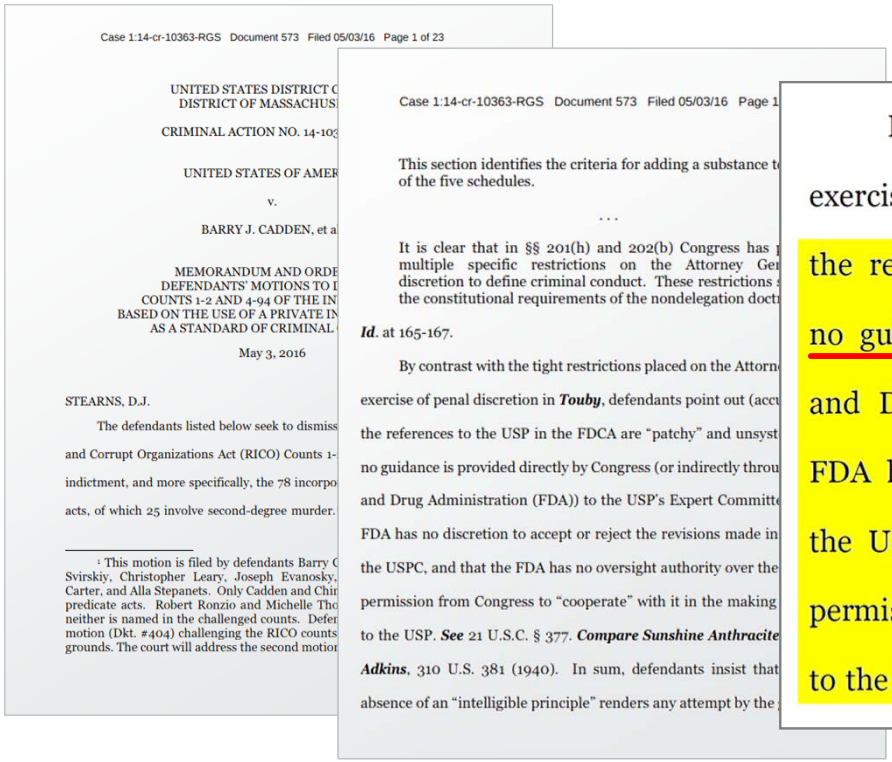
agency to exercise regulatory authority over a major policy question of great economic and political importance, Congress must either: (i) expressly and specifically decide the major policy question itself and delegate to the agency the authority to regulate and enforce; or (ii) expressly and specifically delegate to the agency the authority both to decide

Statement of JUSTICE KAVANAUGH respecting the denial of certiorari.

Source Document: Damon Root, *Kavanaugh Joins Gorsuch in Fight To Revive Nondelegation Doctrine,* Reason (Nov. 25, 2019).

Source Document: *Paul v. United States*, 589 U.S. _____ (2019) (statement of Kavanaugh, J., respecting the denial of certiorari).

What Does This Mean for USP?


Case 1:14-cr-10363-RGS Document 573 Filed 05/03/16 Page 1 of 23

UNITED STATES DISTRICT C
DISTRICT OF MASSACHUS

CRIMINAL ACTION NO. 14-10

UNITED STATES OF AMER

v.

BARRY J. CADDEN, et a

MEMORANDUM AND ORDE
DEFENDANTS' MOTIONS TO I
COUNTS 1-2 AND 4-94 OF THE IN
BASED ON THE USE OF A PRIVATE IN
AS A STANDARD OF CRIMINAL

May 3, 2016

STEARNS, D.J.

The defendants listed below seek to dismiss
and Corrupt Organizations Act (RICO) Counts 1-
indictment, and more specifically, the 78 incorpo
acts, of which 25 involve second-degree murder.

[1] This motion is filed by defendants Barry C
Svirsky, Christopher Leary, Joseph Evanosky,
Carter, and Alla Stepanets. Only Cadden and Chir
predicate acts. Robert Ronzio and Michelle Tho
neither is named in the challenged counts. Defer
motion (Dkt. #404) challenging the RICO counts
grounds. The court will address the second motion

Case 1:14-cr-10363-RGS Document 573 Filed 05/03/16 Page 1

This section identifies the criteria for adding a substance t
of the five schedules.

. . .

It is clear that in §§ 201(h) and 202(b) Congress has
multiple specific restrictions on the Attorney Ge
discretion to define criminal conduct. These restrictions
the constitutional requirements of the nondelegation doct

Id. at 165-167.

By contrast with the tight restrictions placed on the Attorn
exercise of penal discretion in ***Touby***, defendants point out (accu
the references to the USP in the FDCA are "patchy" and unsyst
no guidance is provided directly by Congress (or indirectly throu
and Drug Administration (FDA)) to the USP's Expert Committe
FDA has no discretion to accept or reject the revisions made in
the USPC, and that the FDA has no oversight authority over the
permission from Congress to "cooperate" with it in the making
to the USP. ***See*** 21 U.S.C. § 377. ***Compare Sunshine Anthracite***
Adkins, 310 U.S. 381 (1940). In sum, defendants insist that
absence of an "intelligible principle" renders any attempt by the

United States v. Cadden

By contrast with the tight restrictions placed on the Attorney General's exercise of penal discretion in ***Touby***, defendants point out (accurately) that the references to the USP in the FDCA are "patchy" and unsystematic, that no guidance is provided directly by Congress (or indirectly through the Food and Drug Administration (FDA)) to the USP's Expert Committees, that the FDA has no discretion to accept or reject the revisions made in the USP by the USPC, and that the FDA has no oversight authority over the USPC, only permission from Congress to "cooperate" with it in the making of revisions to the USP. ***See*** 21 U.S.C. § 377. ***Compare Sunshine Anthracite Coal Co. v.***

- Supreme Court likely to decide that USP's standards violate the non-delegation doctrine.
- One lower court has essentially already decided as much.

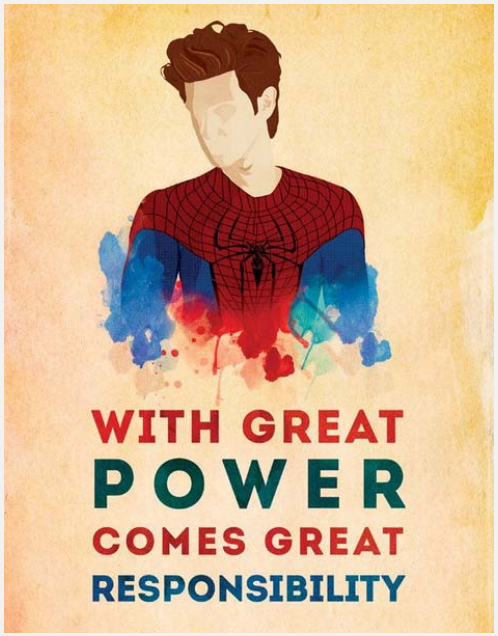
Source Document: *United States v. Cadden*, WL 1948832 at *1 (D. Mass. 2016).

Implications of *Cadden* and *Amtrak* for USP

- Threatens the entire USP system.
- System ripe for legal challenge.
- This would present a compelling test case.
- Renewed emphasis on the non-delegation doctrine from a majority of the Supreme Court.

"With Great Power Comes Great Responsibility": Due Process Concerns

+ usp™ =



The Due Process Clause

- "No person shall be . . . deprived of life, liberty, or property, without due process of law." U.S. CONST. amend. V.
- Due process protects against deprivations by state actors.
- Private entities, such as USP, qualify as a state actor if the government "***participat[es]" in its activities, putting "its power, property and prestige behind" the entity, or when there is "interdependence" between the entity and the state***. *Burton v. Wilmington Parking Auth.*, 365 U.S. 715, 722, 725 (1961) (emphasis added).
- The relationship between USP and the FDA answers to both criteria.

USP, a State Actor, Is Bound by the Due Process Clause

- FDA's relationship with USP is codified in federal law. *See* 21 U.S.C. § 377.
- The actual interdependence between FDA and USP confirms USP's status as a state actor.
  - "Five FDA centers and the Office of the Commissioner have established delegates at USP's Convention, the [USP's] top leadership body" (United States Pharmacopeia, *USP and FDA Working Together To Protect Public Health* (2018));
  - "USP staff maintain executive-level contacts with FDA leadership and routine contacts with FDA's Compendial Operations and Standards Branch through quarterly meetings" (*Id.*);
  - "More than 100 FDA staff participate as government liaisons on USP's Expert Committees and Expert Panels, the scientific bodies that develop and revise USP's written and physical standards" (*Id.*); and
  - "FDA and USP work together to identify areas for monograph or general chapter development . . . ." *Id.*
- USP has gone so far as specifying that FDA officials work with it in their official capacities: "***Government liaisons represent FDA opinions and viewpoints*** (as opposed to other USP volunteers, who represent their own opinions rather than their employers') at public USP meetings such as the Expert Committee Meetings, Expert Panels and Stakeholder Forums." *Id.*

USP Has Violated Its Due Process Obligations

- The U.S. Supreme Court has emphasized that the "fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner.'" *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976).
- Here, USP's efforts to revise Chapters <795> and <797> failed to provide the Coalition's members and the public with a fair opportunity to be heard in a meaningful manner, free from arbitrary decision-making or bias.
  - USP ignored scientific authority and reasoned comments and concerns submitted by Coalition-members.
  - USP's crucial standard-setting operations and procedures are shrouded in secrecy.
  - Neither USP's Bylaws nor its Rules and Procedures of the Council of Experts commit definitively to what procedures or standards USP must follow when revising its General Chapters.

The Administrative Procedure Act ("APA")

- USP's standard-setting procedures fail to satisfy important, well-established strictures of the APA.
- The APA governs how "agencies" of the United States are to develop and issue regulations, rules, and guidance, including through the notice-and-comment process that traditionally defines public rulemaking.
- Because USP is directly and uniquely shaping federal law and policy concerning the use, development, and distribution of pharmaceuticals—a role that is reserved for the government—it is subject to the same constraints imposed upon the government.

USP Has Violated the APA

- USP does not offer sufficient reasons why comments were adopted or rejected. 5 U.S.C. § 553(c).
- USP does not publish the comments that it receives from interested parties or otherwise make them readily available to the public or other interested stakeholders.
- USP's standards are not based on a record demonstrating rational, evidence-based scientific justifications. 5 U.S.C. § 706(2)(A).
- USP has not publicly articulated its rationales for the revised standards. 5 U.S.C. § 552(a).

Conflicts of Interest and the APA

- Under the APA, an unmitigated conflict of interest will render resultant agency action "arbitrary and capricious" in violation of the APA.
- Courts routinely overturn agency action that is tainted by unmitigated conflicts: *Am. Safety Council, Inc. v. U.S.*, 122 Fed. Cl. 426, 443 (2015) (Department of Labor's failure to consider conflicts of interest in taking official agency action was arbitrary and capricious under the APA); *Jacobs Tech. Inc. v. United States*, 100 Fed. Cl. 198, 210 (2011) (Department of Defense subsidiary's failure to account for known conflict of interest issues rendered agency's action arbitrary and capricious under the APA).
- This precise scenario happened recently within the FDA context, and FDA's action was declared to be a violation of the APA.
  - "***FDA erred in determining that the three Challenged Members of the TPSAC did not have financial and appearance conflicts of interest, and second, that therefore the FDA's appointment of those members was arbitrary and capricious, in violation of the APA, and fatally tainted the composition of the TPSAC and its work product, including the Menthol Report***." *Lorillard, Inc. v. United States Food & Drug Admin.*, 56 F. Supp. 3d 37, 40 (D.D.C. 2014), *vacated sub nom. on other grounds R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 810 F.3d 827 (D.C. Cir. 2016).

USP Cannot Regulate as FDA's Proxy

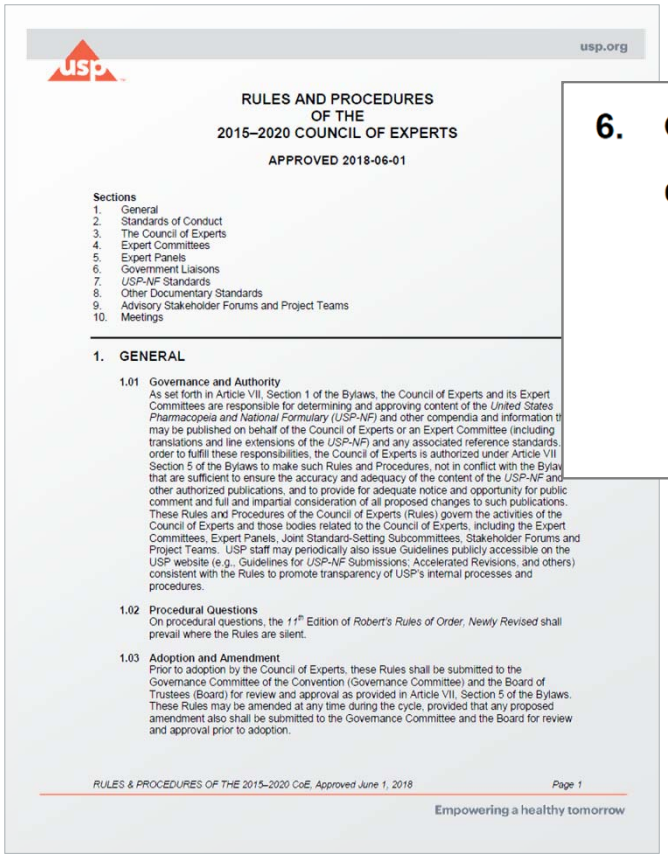
- FDA has dispatched USP to serve as its proxy, regulating on FDA's behalf while circumventing the APA and requirements of notice-and-comment rulemaking that constrain FDA.
- FDA cannot deputize USP to effect what amount to seismic changes in the rules governing the compounding industry, without providing any reasoned justification for doing so or otherwise complying with the most basic and essential requirements of the APA, or adhering to basic principles of due process.
- Congress decides what the law is; FDA cannot use USP to back-channel changes in the law so as to circumvent statutory constraints, as well as public and judicial scrutiny.

Roadmap of the Coalition's Appeal

1. Threshold Legal Concerns
2. **Problems with USP's Development of the Revised Chapters**
3. Problems with the Adequacy of this Appeal Hearing
4. Remand to New, Fairly Informed CEC

Problems with USP's Process: *USP Allowed FDA to Pull its Strings in Arriving at the Revised Chapters*

FDA Is Actively Involved in USP Standard-Setting



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RULES AND PROCEDURES
OF THE
2015–2020 COUNCIL OF EXPERTS

APPROVED 2018-06-01

Sections
1. General
2. Standards of Conduct
3. The Council of Experts
4. Expert Committees
5. Expert Panels
6. Government Liaisons
7. *USP-NF* Standards
8. Other Documentary Standards
9. Advisory Stakeholder Forums and Project Teams
10. Meetings

1. GENERAL

1.01 Governance and Authority
As set forth in Article VII, Section 1 of the Bylaws, the Council of Experts and its Expert Committees are responsible for determining and approving content of the *United States Pharmacopeia and National Formulary (USP-NF)* and other compendia and information t may be published on behalf of the Council of Experts or an Expert Committee (including translations and line extensions of the *USP-NF*) and any associated reference standards. order to fulfill these responsibilities, the Council of Experts is authorized under Article VII Section 5 of the Bylaws to make such Rules and Procedures, not in conflict with the Bylaw that are sufficient to ensure the accuracy and adequacy of the content of the *USP-NF* and other authorized publications, and to provide for adequate notice and opportunity for public comment and full and impartial consideration of all proposed changes to such publications. These Rules and Procedures of the Council of Experts (Rules) govern the activities of the Council of Experts and those bodies related to the Council of Experts, including the Expert Committees, Expert Panels, Joint Standard-Setting Subcommittees, Stakeholder Forums and Project Teams. USP staff may periodically also issue Guidelines publicly accessible on the USP website (e.g., Guidelines for *USP-NF* Submissions; Accelerated Revisions, and others) consistent with the Rules to promote transparency of USP's internal processes and procedures.

1.02 Procedural Questions
On procedural questions, the 11th Edition of *Robert's Rules of Order, Newly Revised* shall prevail where the Rules are silent.

1.03 Adoption and Amendment
Prior to adoption by the Council of Experts, these Rules shall be submitted to the Governance Committee of the Convention (Governance Committee) and the Board of Trustees (Board) for review and approval as provided in Article VII, Section 5 of the Bylaws. These Rules may be amended at any time during the cycle, provided that any proposed amendment also shall be submitted to the Governance Committee and the Board for review and approval prior to adoption.

RULES & PROCEDURES OF THE 2015–2020 CoE, Approved June 1, 2018 Page 1

Empowering a healthy tomorrow

6. GOVERNMENT LIAISONS

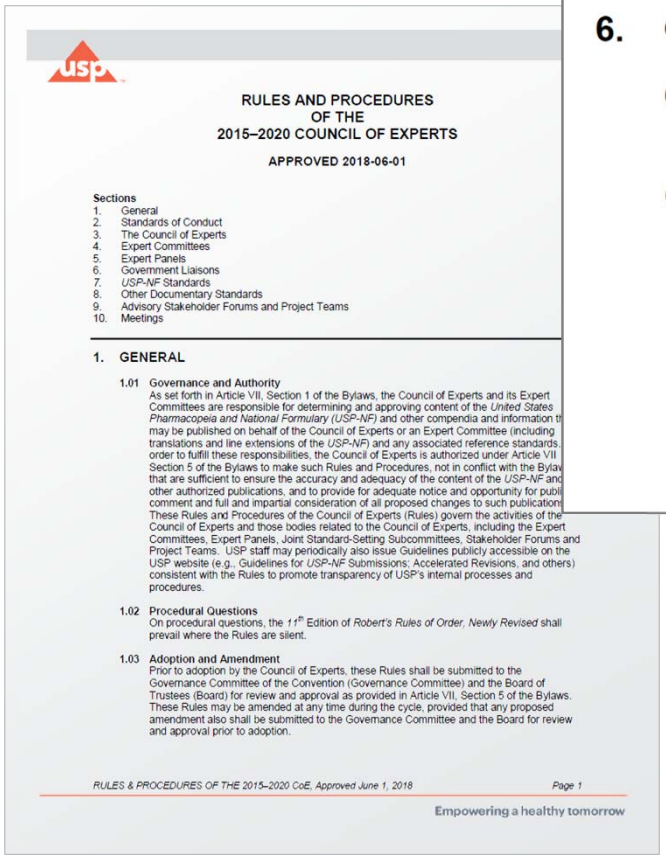
6.01 Role in Standards-Setting Process

Government Liaisons (GLs) are representatives from the United States (U.S.) Food and Drug Administration or other federal or state governmental agencies in the U.S., or from government agencies in other countries. GLs participate in the setting of USP compendial standards of a USP Expert Committee or Expert Panel to which they are assigned and may offer opinions on all facets of the standards including content and implementation. GLs also may be tasked with seeking information or opinions from the agency they represent, and with identifying other representatives of their agency who may have specific subject matter expertise that might be helpful to the Expert Committee or Expert Panel.

- FDA Government Liaisons have a ***guaranteed seat at the table*** in the standard-setting process.
- FDA Government Liaisons' role is to "offer ***opinions on all facets of the standards*** including content and implementation."

Source Document: Rules and Procedures of the 2015-2020 USP Council of Experts (approved 06/01/2018), Sec. 6.01.

FDA Operates Behind Closed Doors with USP



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RULES & PROCEDURES OF THE 2015–2020 CoE, Approved June 1, 2018 Page 1

Empowering a healthy tomorrow

6. GOVERNMENT LIAISONS

6.01 Role in Standards-Setting Process

* * *

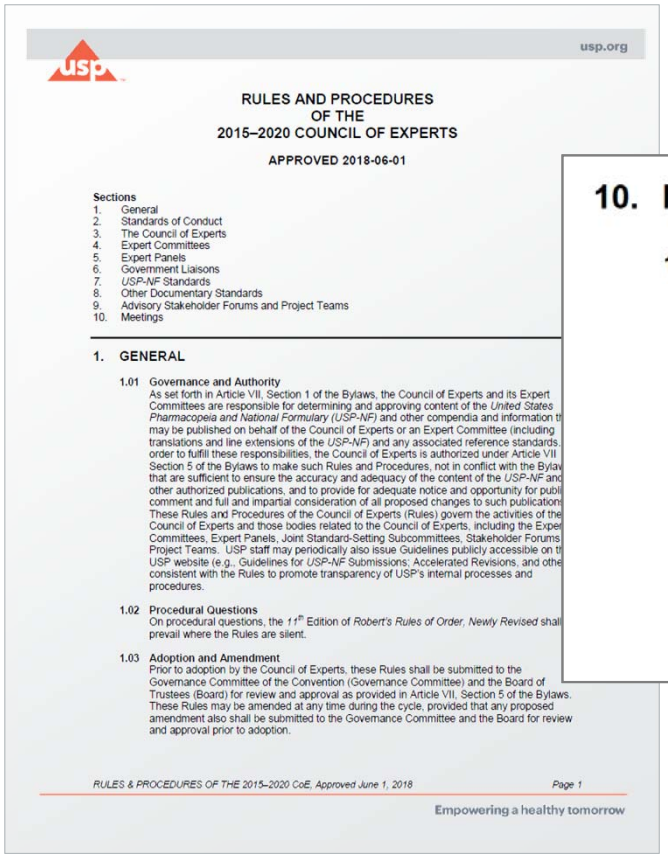
6.02 Responsibilities and Confidentiality

GLs generally receive briefing materials and are allowed to participate in confidential discussions during an Expert Committee or Expert Panel meeting, but they do not vote on USP standards. GLs are required to sign confidentiality agreements allowing them to share information only within their agency as necessary to fulfill their GL responsibilities. Some information provided by USP to GLs may be proprietary, commercial, trade secret and confidential and not subject to public disclosure unless such information is already publicly available. The chair of an Expert Committee or Expert Panel may ask a GL to excuse him or herself during any discussion or deliberation in which the chairperson believes such GL's participation would not be appropriate due to confidentiality, conflict, or other reasons.

- Tellingly, while USP closes certain meetings to the public, it nonetheless ***allows representatives of FDA "to participate in confidential discussions*** during an Expert Committee or Expert Panel meeting."

Source Document: Rules and Procedures of the 2015-2020 USP Council of Experts (approved 06/01/2018), Sec. 6.02.

FDA Operates Behind Closed Doors with USP



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RULES & PROCEDURES OF THE 2015–2020 CoE, Approved June 1, 2018 Page 1

Empowering a healthy tomorrow

10. MEETINGS

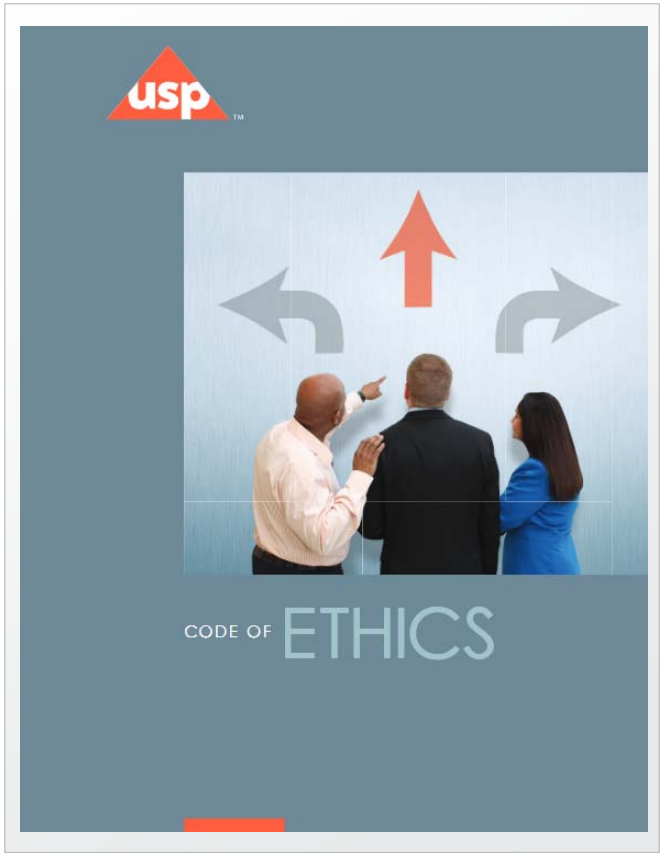
10.01 Expert Committee and Expert Panel Meetings

* * *

(b) Closed Meetings. If the determination is made to close an official meeting, such determination and the reason for closure shall be announced at the beginning of the meeting or during the meeting and noted in the meeting minutes. Any non-member participants (observers, invited guests, etc. described in section 10.03 (a) and (b) below) attending such meeting shall be excused from the meeting. Government Liaisons may participate in closed meetings unless excused by the chairperson for the reasons described in section 6.02 above. All ballot teleconferences held by an Expert Committee, Expert Panel or Joint Standard Setting Subcommittee are considered to be closed meetings to maintain the confidentiality of the information discussed. Meetings of the Council of Experts shall be closed unless otherwise indicated.

Source Document: Rules and Procedures of the 2015-2020 USP Council of Experts (approved 06/01/2018), Sec. 10.01(b).

FDA's Communications with USP Are Shielded from Public Disclosure



Document Disclosure

USP provides disclosure of information and records regarding USP standards-setting activities consistent with:

- The rights of individuals to privacy
- USP's need to protect the confidentiality of trade secrets and other proprietary commercial or financial information
- USP's need to promote frank internal deliberations and to pursue standards-setting activities without disruption

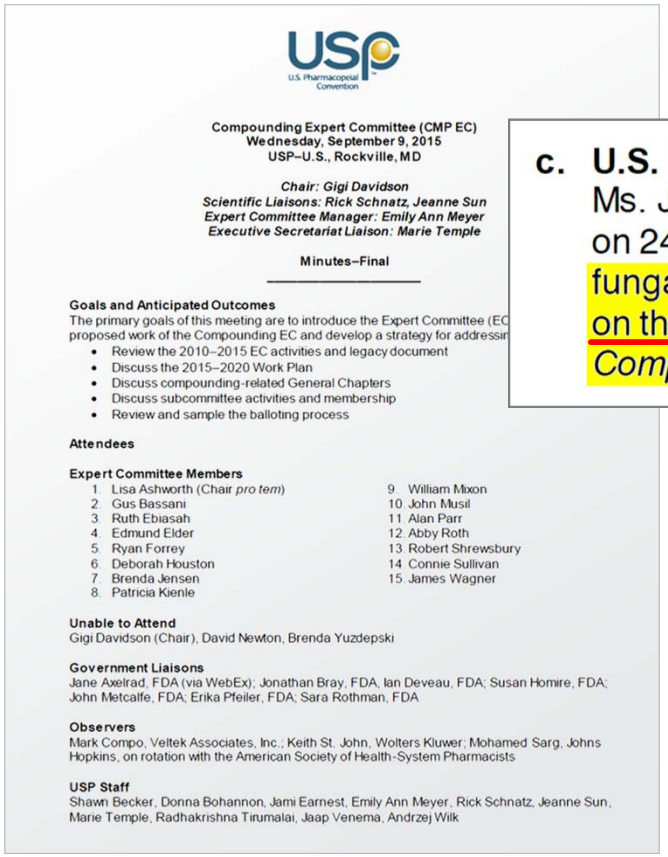
* * *

In addition, communications between USP and third parties relating to standards-setting activities will be made available upon specific written request, including copies of written correspondence to and from third parties and memoranda of telephone conversations and meetings with third parties. Such third-party communications do not include communications of any kind among or between USP staff and members of the Board of Trustees, Council of Experts, or Expert Committees. Furthermore, unless required by law, USP will not disclose documents containing any trade secrets or confidential commercial

Source Document: USP Code of Ethics (2015), p.8.

FDA Secretly Scripted USP's Changes to the Revised Chapters

FDA Secretly Scripted USP's Changes to the Revised Chapters



USP
U.S. Pharmacopeial Convention

Compounding Expert Committee (CMP EC)
Wednesday, September 9, 2015
USP–U.S., Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Rick Schnatz, Jeanne Sun
Expert Committee Manager: Emily Ann Meyer
Executive Secretariat Liaison: Marie Temple

Minutes–Final

Goals and Anticipated Outcomes
The primary goals of this meeting are to introduce the Expert Committee (EC
proposed work of the Compounding EC and develop a strategy for addressir

- Review the 2010–2015 EC activities and legacy document
- Discuss the 2015–2020 Work Plan
- Discuss compounding-related General Chapters
- Discuss subcommittee activities and membership
- Review and sample the balloting process

Attendees

Expert Committee Members

1. Lisa Ashworth (Chair *pro tem*)
2. Gus Bassani
3. Ruth Ebiasah
4. Edmund Elder
5. Ryan Forrey
6. Deborah Houston
7. Brenda Jensen
8. Patricia Kienle
9. William Mixon
10. John Musil
11. Alan Parr
12. Abby Roth
13. Robert Shrewsbury
14. Connie Sullivan
15. James Wagner

Unable to Attend
Gigi Davidson (Chair), David Newton, Brenda Yuzdepski

Government Liaisons
Jane Axelrad, FDA (via WebEx); Jonathan Bray, FDA; Ian Deveau, FDA; Susan Homire, FDA; John Metcalfe, FDA; Erika Pfeiler, FDA; Sara Rothman, FDA

Observers
Mark Compo, Veltek Associates, Inc.; Keith St. John, Wolters Kluwer; Mohamed Sarg, Johns Hopkins, on rotation with the American Society of Health-System Pharmacists

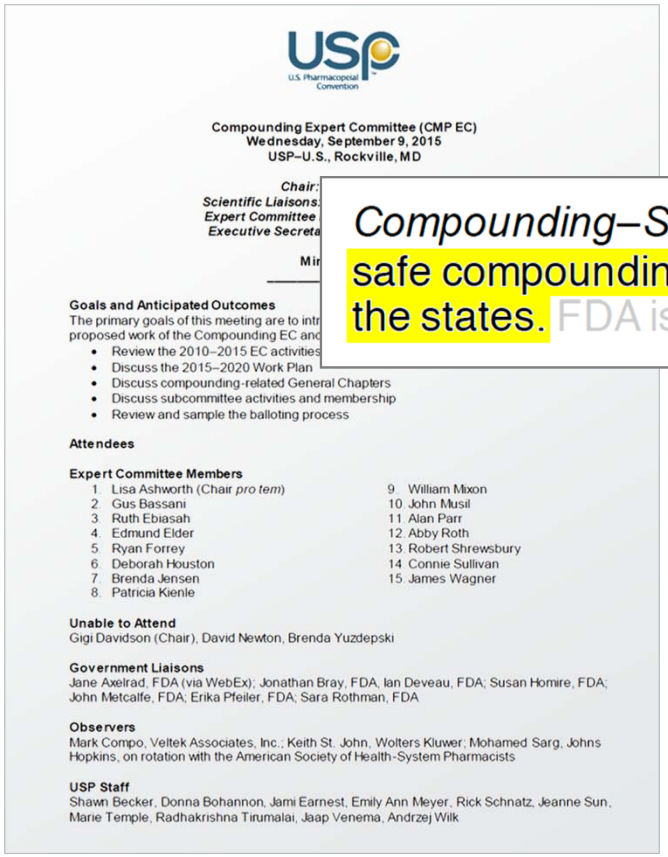
USP Staff
Shawn Becker, Donna Bohannon, Jami Earnest, Emily Ann Meyer, Rick Schnatz, Jeanne Sun, Marie Temple, Radhakrishna Tirumalai, Jaap Venema, Andrzej Wilk

c. U.S. Food and Drug Administration (FDA) Introduction
Ms. Jane Axelrad, the FDA lead on compounding, explained that 90 FDA liaisons serve on 24 USP ECs. As a result of the 2012 New England Compounding Center (NECC) fungal meningitis outbreak, FDA expanded its participation on the CMP EC, specifically on the subcommittee working on General Chapter <797> *Pharmaceutical Compounding–Sterile Preparations* Subcommittee. <797> is critically important for the

- As a result of the 2012 New England Compounding Center ("NECC") fungal meningitis outbreak, ***FDA expanded its participation on the CEC, specifically on the Subcommittee working on General Chapter <797>***.

Source Document: Compounding Expert Committee Meeting Minutes (Sept. 9, 2015), at p.3.

FDA Secretly Scripted USP's Changes to the Revised Chapters



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- Review and sample the balloting process

Attendees

Expert Committee Members

1. Lisa Ashworth (Chair *pro tem*)
2. Gus Bassani
3. Ruth Ebiasah
4. Edmund Elder
5. Ryan Forrey
6. Deborah Houston
7. Brenda Jensen
8. Patricia Kienle
9. William Mixon
10. John Musil
11. Alan Parr
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13. Robert Shrewsbury
14. Connie Sullivan
15. James Wagner

Unable to Attend
Gigi Davidson (Chair), David Newton, Brenda Yuzdepski

Government Liaisons
Jane Axelrad, FDA (via WebEx); Jonathan Bray, FDA; Ian Deveau, FDA; Susan Homire, FDA; John Metcalfe, FDA; Erika Pfeiler, FDA; Sara Rothman, FDA

Observers
Mark Compo, Veltek Associates, Inc.; Keith St. John, Wolters Kluwer; Mohamed Sarg, Johns Hopkins, on rotation with the American Society of Health-System Pharmacists

USP Staff
Shawn Becker, Donna Bohannon, Jami Earnest, Emily Ann Meyer, Rick Schnatz, Jeanne Sun, Marie Temple, Radhakrishna Tirumalai, Jaap Venema, Andrzej Wilk

Compounding–Sterile Preparations Subcommittee. <797> is critically important for the safe compounding of sterile preparations as regulated by the federal government and the states. FDA is making the CMP EC a priority in this cycle and is expanding its

- According to FDA's then-lead on compounding, Jane Axelrad, "***<797> is critically important*** for the safe compounding of sterile preparations as regulated by the federal government and the states."

Source Document: Compounding Expert Committee Meeting Minutes (Sept. 9, 2015), at p.3.

FDA Secretly Scripted USP's Changes to the Revised Chapters

USP
U.S. Pharmacopeial Convention

Compounding Expert Committee (CMP EC)
Meeting #8
Thursday, April 3, 2014
USP Headquarters, Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Rick Schnatz, Jeanne Sun
Expert Committee Manager: Emily Ann Meyer
Executive Secretariat Liaison: Marie Temple

Minutes–Final

Goals and Anticipated Outcomes
- Discuss compounding policy topics
- Discuss subcommittee reports

Attendees

Expert Committee Members
1. Gigi Davidson (Chair)
2. Lisa Ashworth (Vice Chair)
3. Gus Bassani
4. Edmund Elder (via telecon)
5. Maria do Carmo Garcez
6. Deborah Houston
7. Patricia Kienle
8. Keisha Lovoi
9. Linda McElhiney
10. William Mixon
11. David Newton
12. Alan Parr
13. Robert Shrewsbury
14. Keith St. John

Unable to Attend
Regina Peacock

Volunteer Observer
15. David Schuck, Monographs–Small Monographs 1 EC

Government Liaisons
Jonathan Bray, Center for Veterinary Medicine (CVM); Ian DeVeau, Center for Drug Evaluation and Research (CDER); John Metcalfe, CDER; Kristina Peters, CDER; Melissa Schaefer (via WebEx), Centers for Disease Control and Prevention (CDC); Nadine Shehab, CDC (via WebEx); Yichun Sun, CDER

Unable to Attend
Edisa Gozun, CDER; Pamela Lee, CDER; Sanja Modric, CVM

Observers
Richard Friedman, CDER; Jennifer Lamb, Pharmaceutic Labs; Alexander Pytlarz, The Compounding Center; Daire Reese, National Community Pharmacists Association (NCPA); Anne Rogers, NCPA; Elizabeth Russell, National Association of Boards of Pharmacy; Ernesto Samuel, Pharmaceutic Labs; Cynthia Thomas, Becton Dickinson and Company

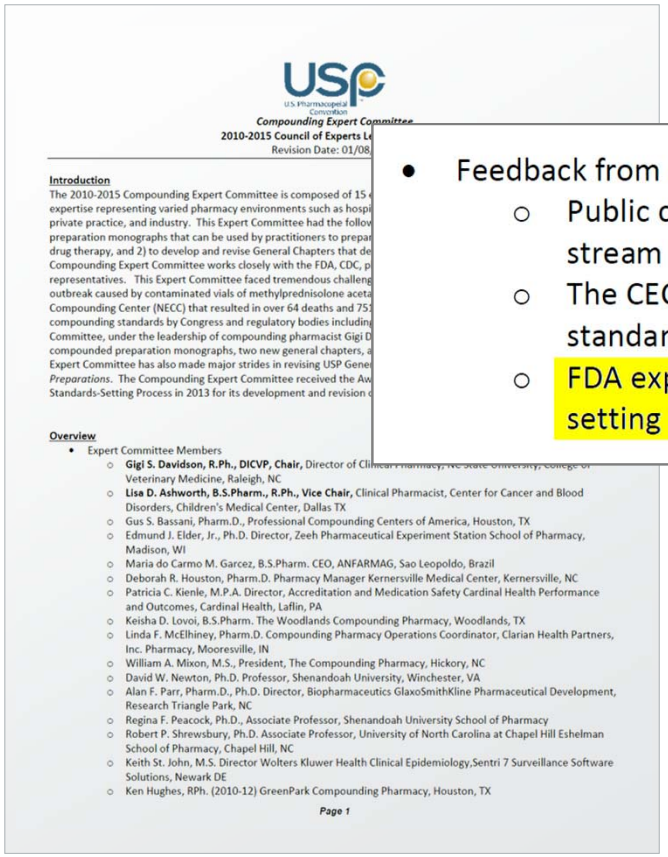
Ms. Susan de Mars summarized USP's dialog with the U.S. Food and Drug Administration (FDA) regarding General Chapter <797> revisions. She noted the following:

- Section 503A in the Drug Quality and Security Act (DQSA) heightened the importance of <797> at the federal and state level.
- FDA and USP want to ensure that the revised General Chapter is as clear as possible.
- FDA has offered an experienced medical writer to assist in revising General Chapter <797>. The FDA medical writer and the USP scientific writer will support the <797> Subcommittee in organizing and drafting the chapter.

- In April 2014, "***FDA . . . offered an experienced medical writer to assist in revising General Chapter <797>***. The FDA medical writer and the USP scientific writer will support the <797> Subcommittee in organizing and drafting the chapter."
- That writer would ultimately hold a pen in helping draft the final language of Chapter <797>.

Source Document: Compounding Expert Committee Meeting Minutes (April 3, 2014), at p.2.

FDA Secretly Scripted USP's Changes to the Revised Chapters



USP
U.S. Pharmacopeial Convention

Compounding Expert Committee

2010-2015 Council of Experts L

Revision Date: 01/08

Introduction

The 2010-2015 Compounding Expert Committee is composed of 15
expertise representing varied pharmacy environments such as hosp
private practice, and industry. This Expert Committee had the follo
preparation monographs that can be used by practitioners to prepa
drug therapy, and 2) to develop and revise General Chapters that de
Compounding Expert Committee works closely with the FDA, CDC, p
representatives. This Expert Committee faced tremendous challeng
outbreak caused by contaminated vials of methylprednisolone aceta
Compounding Center (NECC) that resulted in over 64 deaths and 75
compounding standards by Congress and regulatory bodies includin
Committee, under the leadership of compounding pharmacist Gigi D
compounded preparation monographs, two new general chapters, a
Expert Committee has also made major strides in revising USP Gene
Preparations. The Compounding Expert Committee received the Aw
Standards-Setting Process in 2013 for its development and revision

Overview

- Expert Committee Members
  - **Gigi S. Davidson, R.Ph., DICVP, Chair,** Director of Cli
    Veterinary Medicine, Raleigh, NC
  - **Lisa D. Ashworth, B.S.Pharm., R.Ph., Vice Chair,** Clinical Pharmacist, Center for Cancer and Blood Disorders, Children's Medical Center, Dallas TX
  - Gus S. Bassani, Pharm.D., Professional Compounding Centers of America, Houston, TX
  - Edmund J. Elder, Jr., Ph.D. Director, Zeeh Pharmaceutical Experiment Station School of Pharmacy, Madison, WI
  - Maria do Carmo M. Garcez, B.S.Pharm. CEO, ANFARMAG, Sao Leopoldo, Brazil
  - Deborah R. Houston, Pharm.D. Pharmacy Manager Kernersville Medical Center, Kernersville, NC
  - Patricia C. Kienle, M.P.A. Director, Accreditation and Medication Safety Cardinal Health Performance and Outcomes, Cardinal Health, Laflin, PA
  - Keisha D. Lovoi, B.S.Pharm. The Woodlands Compounding Pharmacy, Woodlands, TX
  - Linda F. McElhiney, Pharm.D. Compounding Pharmacy Operations Coordinator, Clarian Health Partners, Inc. Pharmacy, Mooresville, IN
  - William A. Mixon, M.S., President, The Compounding Pharmacy, Hickory, NC
  - David W. Newton, Ph.D. Professor, Shenandoah University, Winchester, VA
  - Alan F. Parr, Pharm.D., Ph.D. Director, Biopharmaceutics GlaxoSmithKline Pharmaceutical Development, Research Triangle Park, NC
  - Regina F. Peacock, Ph.D., Associate Professor, Shenandoah University School of Pharmacy
  - Robert P. Shrewsbury, Ph.D. Associate Professor, University of North Carolina at Chapel Hill Eshelman School of Pharmacy, Chapel Hill, NC
  - Keith St. John, M.S. Director Wolters Kluwer Health Clinical Epidemiology,Sentri 7 Surveillance Software Solutions, Newark DE
  - Ken Hughes, RPh. (2010-12) GreenPark Compounding Pharmacy, Houston, TX

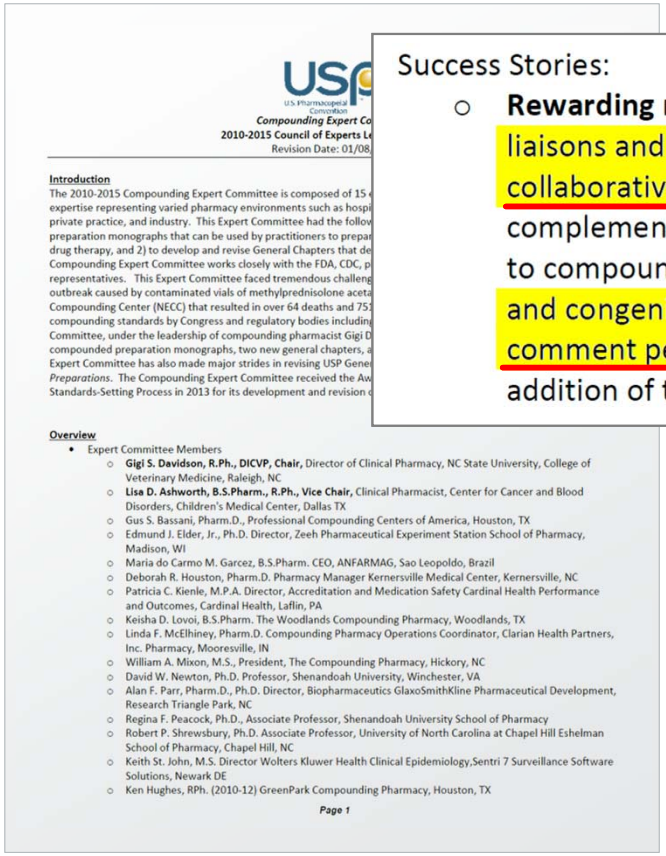
Page 1

- Feedback from stakeholders (e.g., industry, regulators, etc.)
  - Public comments on <800> were in excess of 3000 for the initial publication in PF and continue to stream in following the second publication in PF 41(2).
  - The CEC also received requests from professional organizations to exempt their stakeholders from standard practices established in <797> and <800>.
  - FDA expressed appreciation for the weekly meetings with USP and collegial working relationship in setting compounding standards.

- Beginning in the 2010-2015 cycle, FDA and USP started having undisclosed ***private weekly meetings*** to discuss "setting compounding standards."

Source Document: 2010-2015 Compounding Expert Committee Legacy Document (Jan. 8, 2015), at p.9.

FDA Secretly Scripted USP's Changes to the Revised Chapters



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  - Keith St. John, M.S. Director Wolters Kluwer Health Clinical Epidemiology,Sentri 7 Surveillance Software Solutions, Newark DE
  - Ken Hughes, RPh. (2010-12) GreenPark Compounding Pharmacy, Houston, TX

Page 1

Success Stories:

- **Rewarding relationship with FDA and CDC**: In spite of a rough start, the relationship between FDA liaisons and the Compounding Expert Committee members has evolved to a very strong and collaborative partnership. The NECC tragedy and subsequent compounding legislation spotlighted the complementary roles that USP standards and FDA regulations have in ensuring that patients have access to compounds of known high quality. To that end, CEC members and FDA liaisons have worked diligently and congenially to reach consensus on proposed revisions and new standards prior to the public comment period in PF. A similarly positive relationship with CDC is also evolving on the CEC following addition of two liaisons from the CDC.

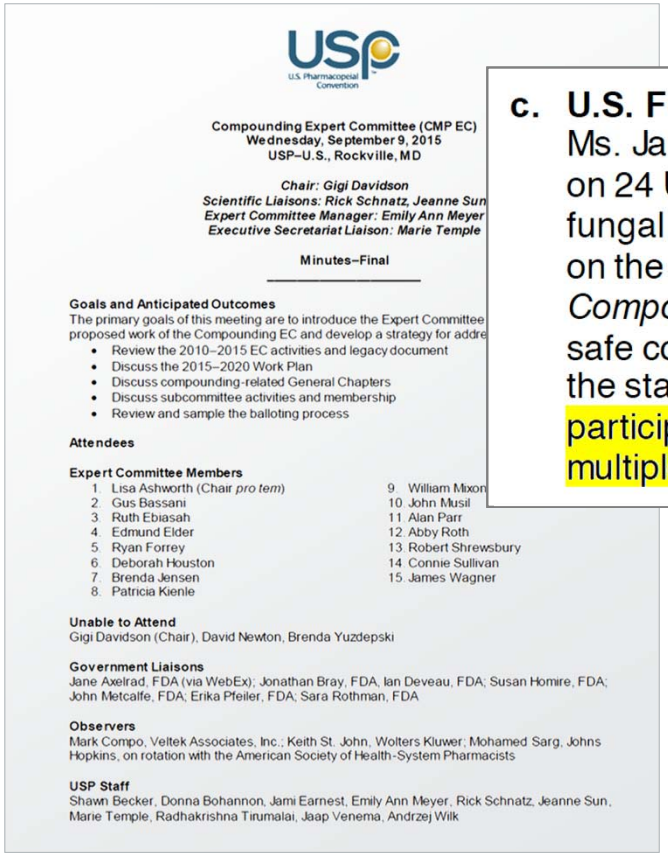
- During the 2010-2015 cycle, USP's and FDA's relationship started out "rough," but ultimately "evolved to a very ***strong and collaborative partnership***."
- By January 2015, CEC members and FDA Government Liaisons had already "***reach[ed] consensus*** on proposed revisions and new standards ***prior to the public comment period***."

Source Document: 2010-2015 Compounding Expert Committee Legacy Document (Jan. 8, 2015), at p.8.

FDA Secretly Scripted USP's Changes to the Revised Chapters

- Thus, long before the standards for <797> were even released to the public for comment, FDA and USP had already come to an agreement, after years of weekly meetings, on what those precise standards should be.

FDA Secretly Scripted USP's Changes to the Revised Chapters



Compounding Expert Committee (CMP EC)
Wednesday, September 9, 2015
USP–U.S., Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Rick Schnatz, Jeanne Sun
Expert Committee Manager: Emily Ann Meyer
Executive Secretariat Liaison: Marie Temple

Minutes–Final

Goals and Anticipated Outcomes
The primary goals of this meeting are to introduce the Expert Committee proposed work of the Compounding EC and develop a strategy for addre

- Review the 2010–2015 EC activities and legacy document
- Discuss the 2015–2020 Work Plan
- Discuss compounding-related General Chapters
- Discuss subcommittee activities and membership
- Review and sample the balloting process

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2. Gus Bassani
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15. James Wagner

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Government Liaisons
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Observers
Mark Compo, Veltek Associates, Inc.; Keith St. John, Wolters Kluwer; Mohamed Sarg, Johns Hopkins, on rotation with the American Society of Health-System Pharmacists

USP Staff
Shawn Becker, Donna Bohannon, Jami Earnest, Emily Ann Meyer, Rick Schnatz, Jeanne Sun, Marie Temple, Radhakrishna Tirumalai, Jaap Venema, Andrzej Wilk

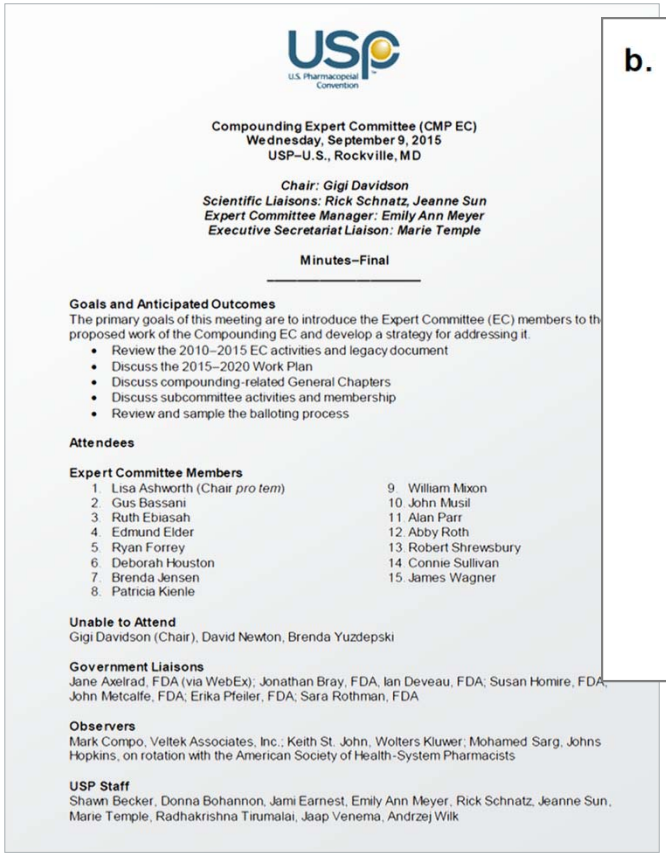
c. U.S. Food and Drug Administration (FDA) Introduction

Ms. Jane Axelrad, the FDA lead on compounding, explained that 90 FDA liaisons serve on 24 USP ECs. As a result of the 2012 New England Compounding Center (NECC) fungal meningitis outbreak, FDA expanded its participation on the CMP EC, specifically on the subcommittee working on General Chapter <797> *Pharmaceutical Compounding–Sterile Preparations* Subcommittee. <797> is critically important for the safe compounding of sterile preparations as regulated by the federal government and the states. FDA is making the CMP EC a priority in this cycle and is expanding its participation by adding two FDA liaisons to identify cross-cutting policy issues that affect multiple subcommittees. Ms. Edisa Gozun will be the CMP EC's central point of contact.

- By September 2015, FDA had "expanded its participation" on the CEC and announced that it was ***unilaterally*** "adding two FDA liaisons" to the committee, bringing the total number of FDA Government Liaisons to eight.

Source Document: Compounding Expert Committee Meeting Minutes (Sept. 9, 2015), at p.3.

FDA Secretly Scripted USP's Changes to the Revised Chapters



USP
U.S. Pharmacopeial Convention

Compounding Expert Committee (CMP EC)
Wednesday, September 9, 2015
USP–U.S., Rockville, MD

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Minutes–Final

Goals and Anticipated Outcomes
The primary goals of this meeting are to introduce the Expert Committee (EC) members to th proposed work of the Compounding EC and develop a strategy for addressing it.

- Review the 2010–2015 EC activities and legacy document
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b. Creation of Subcommittees

Dr. Sun reported that EC members and FDA liaisons volunteered to serve on EC Subcommittees as follows:

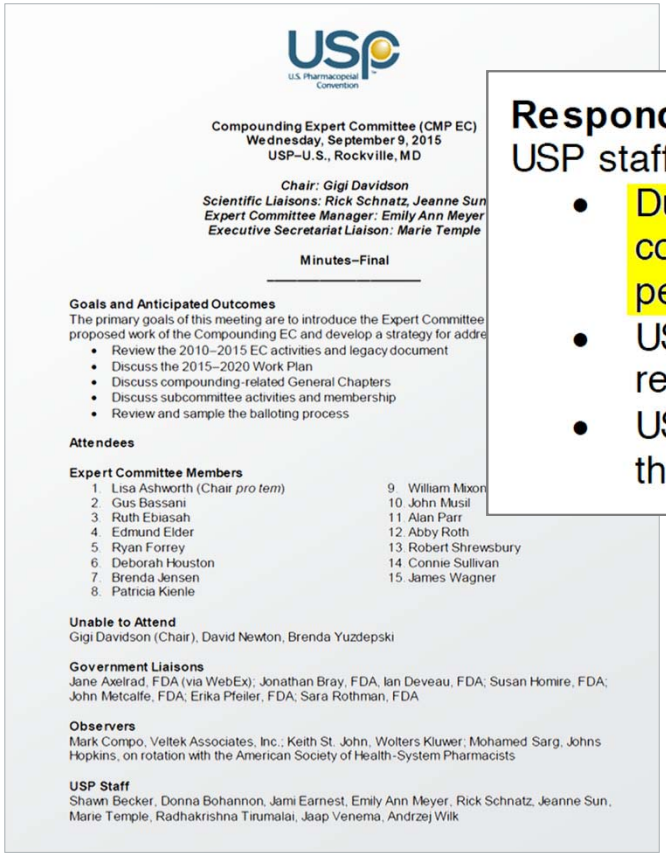
1) **<795> Pharmaceutical Compounding–Nonsterile Preparations**
Chair: Bob Shrewsbury
EC Members: Gus Bassani, Gigi Davidson, John Musil, David Newton, Alan Parr, Brenda Yuzdepski
FDA Liaisons: Jane Axelrad, Jonathan Bray, Ian Deveau , Susan Homire, John Metcalfe, Erika Pfeiler

2) **<797> Pharmaceutical Compounding–Sterile Preparations**
Chair: Gigi Davidson
EC Members: Deb Houston, Patti Kienle, Bill Mixon, Dave Newton, Abby Roth, Connie Sullivan, Jim Wagner
FDA Liaisons: Jane Axelrad, Jonathan Bray, Ian Deveau, Susan Homire, John Metcalfe, Erika Pfeiler

- In September 2015, USP created the <797> and <795> Subcommittees for 2015-2020 cycle—both of which were overrun by FDA Government Liaisons.

Source Document: Compounding Expert Committee Meeting Minutes (Sept. 9, 2015), at p.12.

FDA Secretly Scripted USP's Changes to the Revised Chapters



USP
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Responding to Public Comments

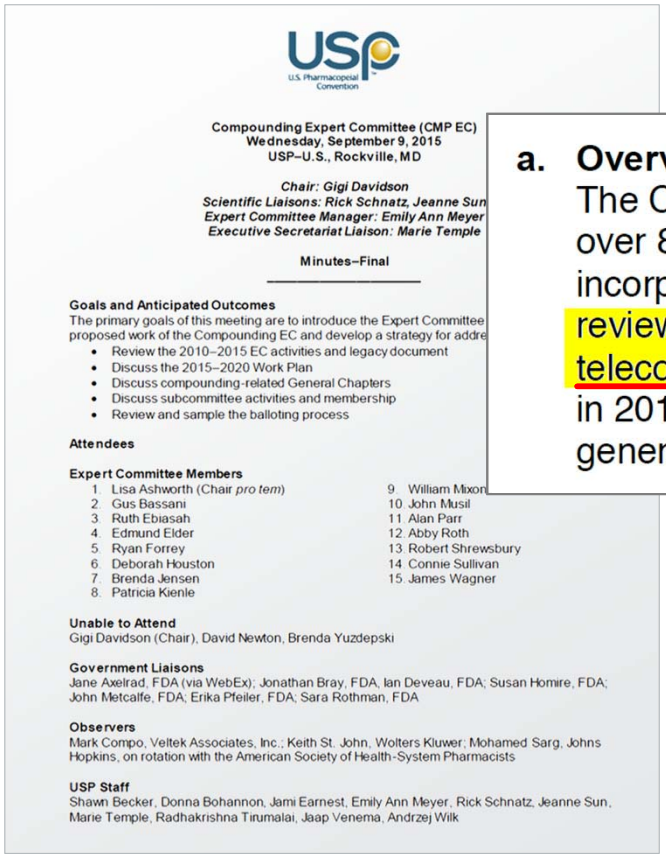
USP staff clarified the following:

- Due to the high volume of comments expected, USP staff will distribute the comments to EC members and government liaisons throughout the comment period.
- USP staff will compile all comments received in a spreadsheet to facilitate EC review after the comment period closes.
- USP staff will ask commenters who do not provide line numbers to provide the line numbers relevant to their comments.

- During the 2015-2020 cycle, the FDA Government Liaisons' core role on the Chapter <797> Subcommittee was seemingly to push the 2010-2015 Subcommittee's revisions through to completion, including by ***reviewing public comments***.

Source Document: Compounding Expert Committee Meeting Minutes (Sept. 9, 2015), at p.5.

FDA Secretly Scripted USP's Changes to the Revised Chapters



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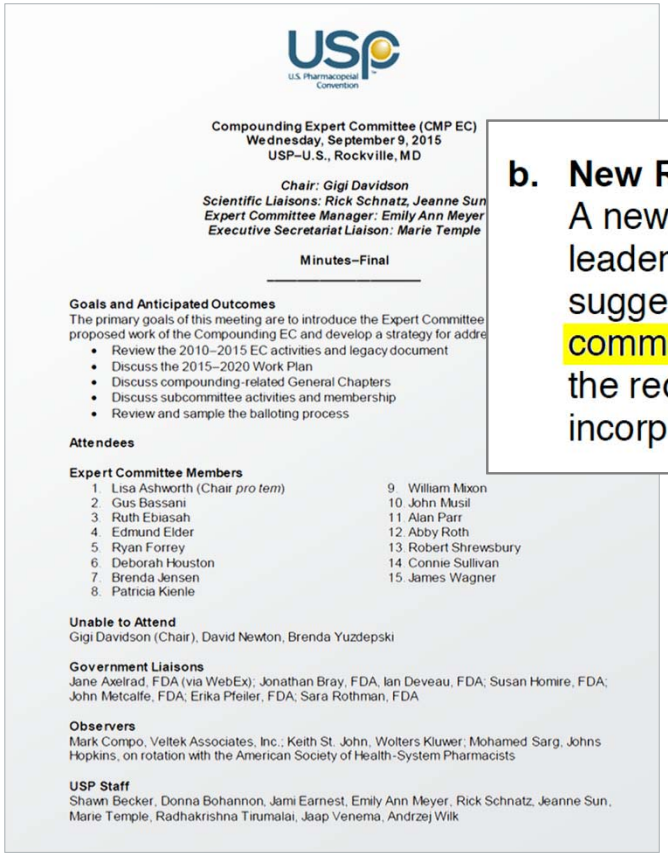
a. Overview of Revision Process Timeline

The Chair explained that she and the Vice Chair were in the process of reviewing the over 8,000 public comments received on <797>, and they have taken a first pass at incorporating the comments by section. EC members and Government Liaisons are reviewing the comments and proposed responses, section by section, in weekly teleconferences. USP will convene roundtables with allergists and radiopharmacists in 2017 to address their unique concerns. The EC has not discussed whether the general chapter will be republished in *PF*.

- By September 2016, the Chapter <797> Chair, Vice-Chair, <797> Subcommittee members, and FDA Government Liaisons were having ***weekly teleconferences*** to determine which comments to incorporate, how to incorporate them, and how to respond to commenters.

Source Document: Compounding Expert Committee Meeting Minutes (Sept. 20, 2016), at p.12.

FDA Secretly Scripted USP's Changes to the Revised Chapters



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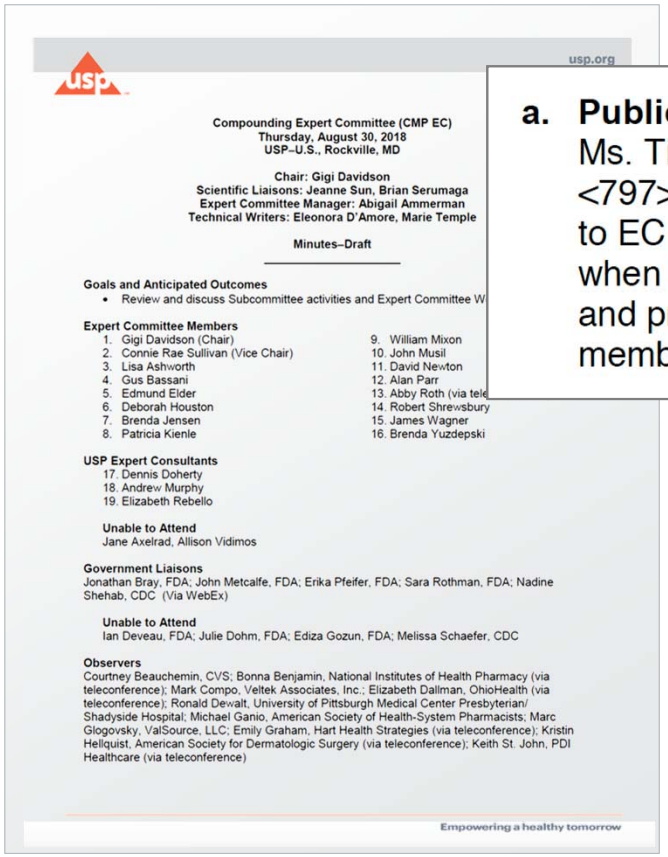
b. New Revision Process Instituted

A new process for revision was adopted to improve efficiency which involved the EC leadership (i.e., Chair, Vice Chair, and USP staff) incorporating public comment suggestions into a redline draft, which is sent to EC members for review and comment. EC members were given 2 weeks to provide comments and feedback on the redline draft to EC leadership. EC member feedback and comments are incorporated into the draft and sent to the Scientific Writer for cleanup and editing.

- Although the weekly conference calls were seemingly abandoned by September 2017, ***the FDA Government Liaisons apparently still had the opportunity to review and comment*** on the public comments received.

Source Document: Compounding Expert Committee Meeting Minutes (May 22, 2017), at p.5.

FDA Secretly Scripted USP's Changes to the Revised Chapters



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Compounding Expert Committee (CMP EC)
Thursday, August 30, 2018
USP–U.S., Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Jeanne Sun, Brian Serumaga
Expert Committee Manager: Abigail Ammerman
Technical Writers: Eleonora D'Amore, Marie Temple

Minutes–Draft

Goals and Anticipated Outcomes
- Review and discuss Subcommittee activities and Expert Committee W

Expert Committee Members
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2. Connie Rae Sullivan (Vice Chair)
3. Lisa Ashworth
4. Gus Bassani
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11. David Newton
12. Alan Parr
13. Abby Roth (via tele
14. Robert Shrewsbury
15. James Wagner
16. Brenda Yuzdepski

USP Expert Consultants
17. Dennis Doherty
18. Andrew Murphy
19. Elizabeth Rebello

Unable to Attend
Jane Axelrad, Allison Vidimos

Government Liaisons
Jonathan Bray, FDA; John Metcalfe, FDA; Erika Pfeifer, FDA; Sara Rothman, FDA; Nadine Shehab, CDC (Via WebEx)

Unable to Attend
Ian Deveau, FDA; Julie Dohm, FDA; Ediza Gozun, FDA; Melissa Schaefer, CDC

Observers
Courtney Beauchemin, CVS; Bonna Benjamin, National Institutes of Health Pharmacy (via teleconference); Mark Compo, Veltek Associates, Inc.; Elizabeth Dallman, OhioHealth (via teleconference); Ronald Dewalt, University of Pittsburgh Medical Center Presbyterian/ Shadyside Hospital; Michael Ganio, American Society of Health-System Pharmacists; Marc Glogovsky, ValSource, LLC; Emily Graham, Hart Health Strategies (via teleconference); Kristin Hellquist, American Society for Dermatologic Surgery (via teleconference); Keith St. John, PDI Healthcare (via teleconference)

Empowering a healthy tomorrow

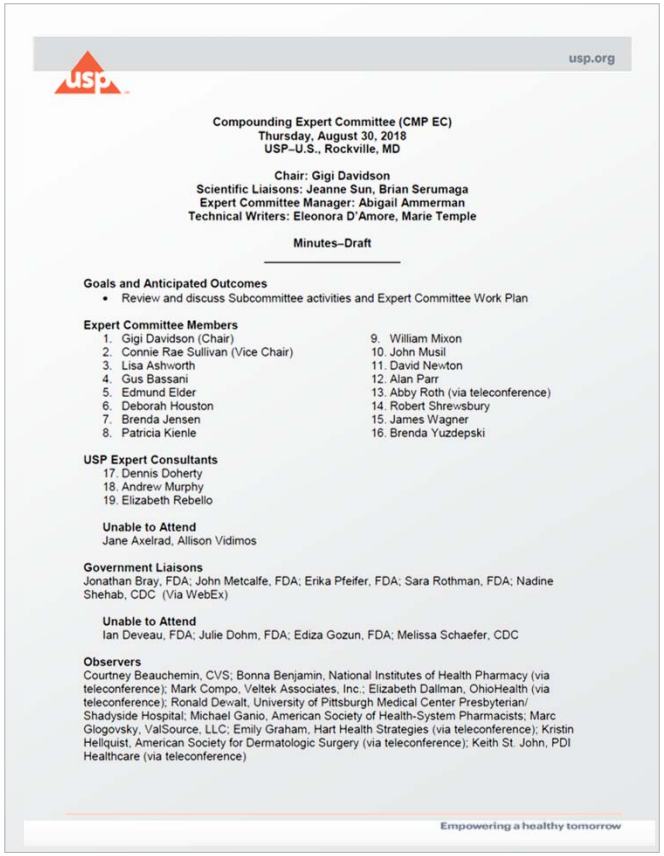
a. Public Comments

Ms. Tiffany Chan noted that as of August 23, 2018, USP received 217 comments on the <797> revision proposal. Dr. Sun noted that she will send five sets of public comments to EC members. The comments will be organized into Excel spreadsheets based on when the comments were received. The Chair and Vice Chair will review the comments and propose how to address them. Then the entire EC will discuss specific topics. EC members may download the <797> revision proposal from USP.org.

- The FDA Government Liaisons' involvement in the comment review process for Chapter <797> continued into the second round of comments, when USP clarified that "the entire [Expert Committee]"—***including, ostensibly, the FDA Government Liaisons***—would "discuss specific topics" raised in the comments.

Source Document: Compounding Expert Committee Meeting Minutes (Aug. 30, 2018), at p.16.

FDA Secretly Scripted USP's Changes to the Revised Chapters



usp.org

Compounding Expert Committee (CMP EC)
Thursday, August 30, 2018
USP–U.S., Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Jeanne Sun, Brian Serumaga
Expert Committee Manager: Abigail Ammerman
Technical Writers: Eleonora D'Amore, Marie Temple

Minutes–Draft

Goals and Anticipated Outcomes
- Review and discuss Subcommittee activities and Expert Committee Work Plan

Expert Committee Members
1. Gigi Davidson (Chair)
2. Connie Rae Sullivan (Vice Chair)
3. Lisa Ashworth
4. Gus Bassani
5. Edmund Elder
6. Deborah Houston
7. Brenda Jensen
8. Patricia Kienle
9. William Mixon
10. John Musil
11. David Newton
12. Alan Parr
13. Abby Roth (via teleconference)
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USP Expert Consultants
17. Dennis Doherty
18. Andrew Murphy
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Unable to Attend
Jane Axelrad, Allison Vidimos

Government Liaisons
Jonathan Bray, FDA; John Metcalfe, FDA; Erika Pfeifer, FDA; Sara Rothman, FDA; Nadine Shehab, CDC (Via WebEx)

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Ian Deveau, FDA; Julie Dohm, FDA; Ediza Gozun, FDA; Melissa Schaefer, CDC

Observers
Courtney Beauchemin, CVS; Bonna Benjamin, National Institutes of Health Pharmacy (via teleconference); Mark Compo, Veltek Associates, Inc.; Elizabeth Dallman, OhioHealth (via teleconference); Ronald Dewalt, University of Pittsburgh Medical Center Presbyterian/ Shadyside Hospital; Michael Ganio, American Society of Health-System Pharmacists; Marc Glogovsky, ValSource, LLC; Emily Graham, Hart Health Strategies (via teleconference); Kristin Hellquist, American Society for Dermatologic Surgery (via teleconference); Keith St. John, PDI Healthcare (via teleconference)

Empowering a healthy tomorrow

Sterility Testing of Aqueous Solutions
FDA Liaisons noted the following:

- A nonsterile drug could have a microbial contamination in the short term. If the microbial load is capable of growth, it could become dangerous the longer the drug is held.
- If a preservative is used and <51> testing is not conducted, the compounder would not know if the preservative will be effective for the stability period.
- To extend the BUD of an FDA-approved aqueous solution, a preservative or self-preserving API and <51> testing would be needed.
- The 14-day BUD for non-preserved aqueous dosage forms should be retained.

- FDA Government Liaisons were also heavily involved in the revisions to Chapter <795>, most of which came during the 2015-2020 cycle.
- For example, in an August 2018 CEC meeting, ***FDA Government Liaisons provided extensive input on the sterility testing of aqueous solutions***—one of the key issues in this appeal.

Source Document: Compounding Expert Committee Meeting Minutes (Aug. 30, 2018), at p.15.

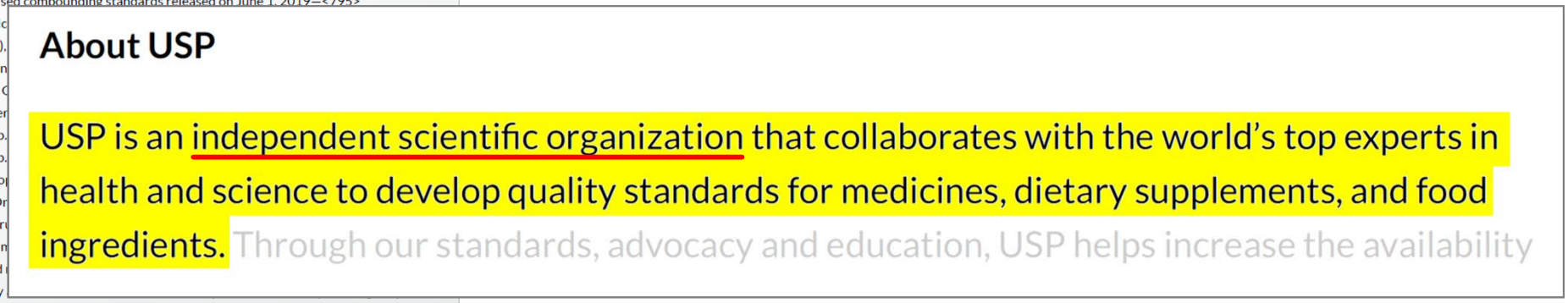
USP Broke Its Purported Commitment to "Independence"

USP Publishes Notice of Intent to Revise Compounding Standards

Rockville, Md., September 23, 2019 — USP published a Notice of Intent To Revise (NITR) (https://www.uspnf.com/notices/compounding-chapters-postponement) for the new and revised compounding standards released on June 1, 2019—<795>

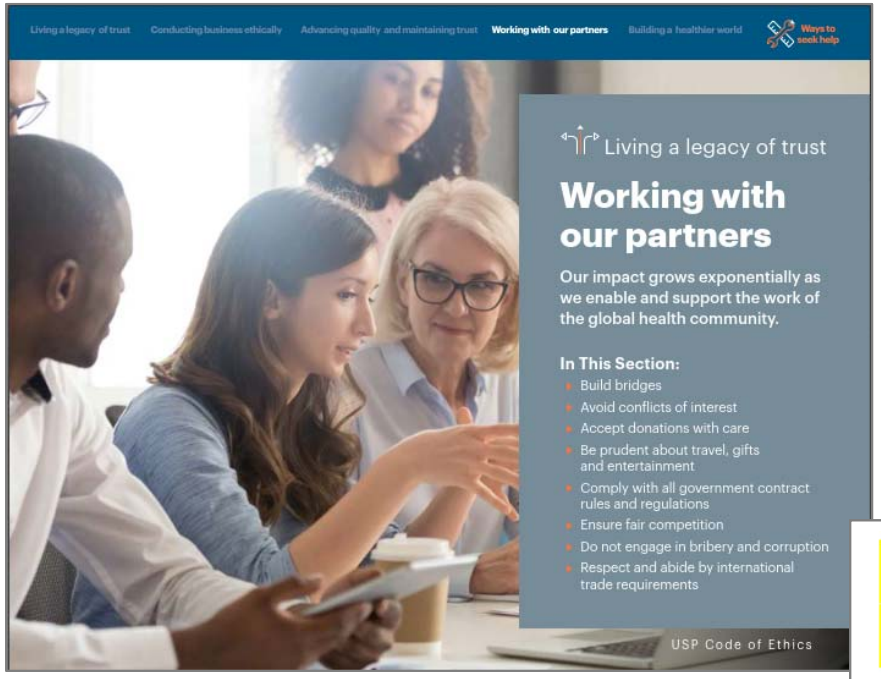
About USP

USP is an independent scientific organization that collaborates with the world's top experts in health and science to develop quality standards for medicines, dietary supplements, and food ingredients. Through our standards, advocacy and education, USP helps increase the availability of quality medicines, supplements and food for billions of people worldwide. For more information about USP, visit www.usp.org



Source Document: *USP Publishes Notice of Intent to Revise Compounding Standards*, USP.org (Sept. 23, 2019).

USP Broke Its Purported Commitment to "Independence"



USP's reputation depends on our independence. As an organization, we must avoid conflicts of interest that interfere or appear to interfere with our impartiality and objectivity. As individuals, we must avoid conflicts

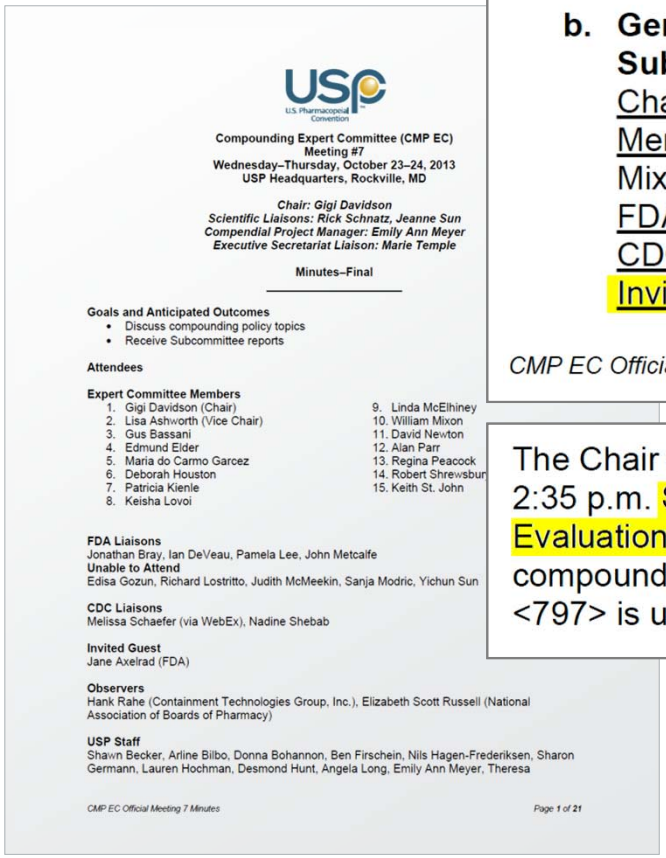
Source Document: Working With Our Partners, USP.org, at p.3.

Case Study: Jane Axelrad's Secretive Dealings with USP

Jane Axelrad

- Long-time FDA employee.
- Joined FDA in 1991.
- From 1995-2012, served as the Director of the Office of Regulatory Policy in FDA's Center for Drug Evaluation and Research ("CDER").
- In 2012, became the Associate Director for Policy in CDER.

Case Study: Jane Axelrad's Secretive Dealings with USP



USP
U.S. Pharmacopeial Convention

Compounding Expert Committee (CMP EC)
Meeting #7
Wednesday–Thursday, October 23–24, 2013
USP Headquarters, Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Rick Schnatz, Jeanne Sun
Compendial Project Manager: Emily Ann Meyer
Executive Secretariat Liaison: Marie Temple

Minutes–Final

Goals and Anticipated Outcomes
- Discuss compounding policy topics
- Receive Subcommittee reports

Attendees

Expert Committee Members
1. Gigi Davidson (Chair)
2. Lisa Ashworth (Vice Chair)
3. Gus Bassani
4. Edmund Elder
5. Maria do Carmo Garcez
6. Deborah Houston
7. Patricia Kienle
8. Keisha Lovoi
9. Linda McElhiney
10. William Mixon
11. David Newton
12. Alan Parr
13. Regina Peacock
14. Robert Shrewsbur
15. Keith St. John

FDA Liaisons
Jonathan Bray, Ian DeVeau, Pamela Lee, John Metcalfe
Unable to Attend
Edisa Gozun, Richard Lostritto, Judith McMeekin, Sanja Modric, Yichun Sun

CDC Liaisons
Melissa Schaefer (via WebEx), Nadine Shebab

Invited Guest
Jane Axelrad (FDA)

Observers
Hank Rahe (Containment Technologies Group, Inc.), Elizabeth Scott Russell (National Association of Boards of Pharmacy)

USP Staff
Shawn Becker, Arline Bilbo, Donna Bohannon, Ben Firschein, Nils Hagen-Frederiksen, Sharon Germann, Lauren Hochman, Desmond Hunt, Angela Long, Emily Ann Meyer, Theresa

CMP EC Official Meeting 7 Minutes *Page 1 of 21*

b. General Chapter <797> *Pharmaceutical Compounding–Sterile Preparations*
Subcommittee
Chair: Gigi Davidson
Members: Deborah Houston, Patricia Kienle, Keisha Lovoi, Linda McElhiney, William Mixon, Dave Newton, Keith St. John
FDA Liaisons: Jonathan Bray, Pamela Lee, John Metcalfe, Kristina Peters
CDC Liaisons: Nadine Shaw, Melissa Shaffer (via WebEx)
Invited guest: Jane Axelrad, FDA

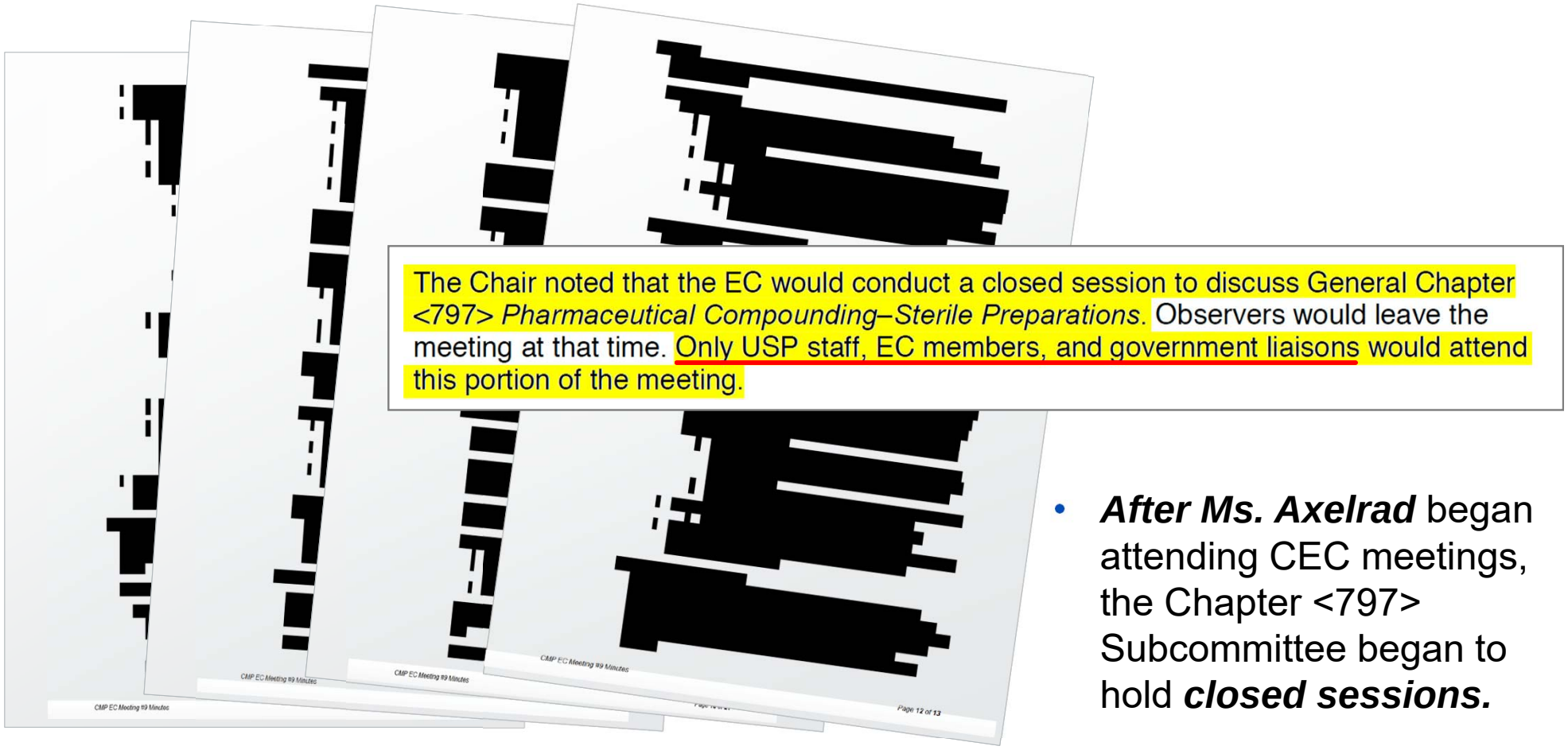
CMP EC Official Meeting 7 Minutes *Page **4** of **21***

The Chair convened the open meeting of the General Chapter <797> Subcommittee at 2:35 p.m. She welcomed Ms. Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research (CDER) at FDA. Ms. Axelrad is the FDA lead on pharmacy compounding. Ms. Axelrad thanked the EC for inviting her to attend and explained that <797> is used by many states to regulate sterile compounding.

- On behalf of FDA, Ms. Axelrad begins consulting for the CEC from October 2013 forward in connection with the revisions for <797> as an "**invited guest**."

Source Document: Compounding Expert Committee Meeting Minutes (Oct. 23-24, 2013), at p.4-5.

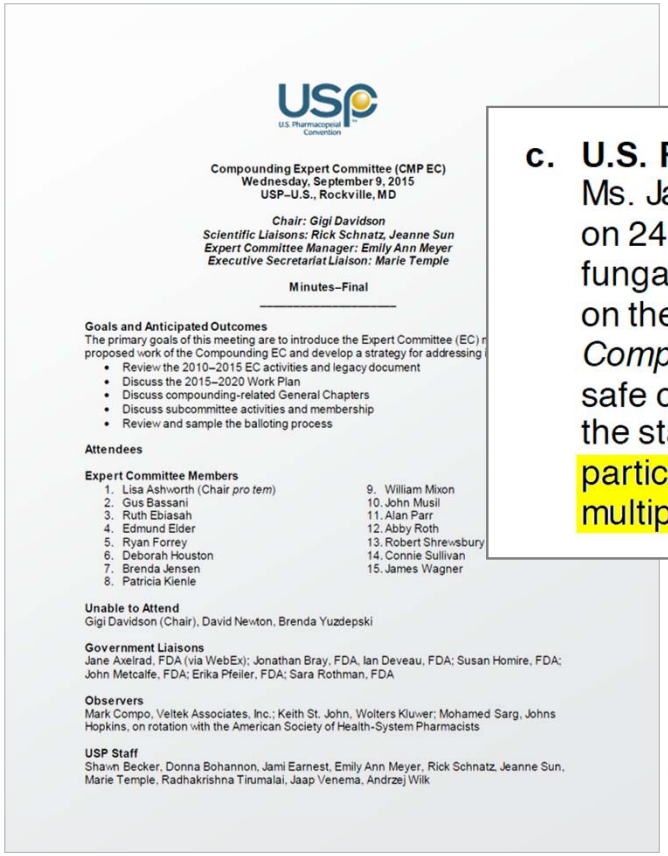
Case Study: Jane Axelrad's Secretive Dealings with USP



- ***After Ms. Axelrad*** began attending CEC meetings, the Chapter <797> Subcommittee began to hold ***closed sessions.***

Source Documents: Compounding Expert Committee Meeting Minutes (Oct. 30, 2014), at p.15-21; Compounding Expert Committee Meeting Minutes (May 5, 2015), at p.11-13.

Case Study: Jane Axelrad's Secretive Dealings with USP



USP
U.S. Pharmacopeial Convention

Compounding Expert Committee (CMP EC)
Wednesday, September 9, 2015
USP–U.S., Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Rick Schnatz, Jeanne Sun
Expert Committee Manager: Emily Ann Meyer
Executive Secretariat Liaison: Marie Temple

Minutes–Final

Goals and Anticipated Outcomes
The primary goals of this meeting are to introduce the Expert Committee (EC) r
proposed work of the Compounding EC and develop a strategy for addressing
- Review the 2010–2015 EC activities and legacy document
- Discuss the 2015–2020 Work Plan
- Discuss compounding-related General Chapters
- Discuss subcommittee activities and membership
- Review and sample the balloting process

Attendees

Expert Committee Members
1. Lisa Ashworth (Chair *pro tem*)
2. Gus Bassani
3. Ruth Ebiasah
4. Edmund Elder
5. Ryan Forrey
6. Deborah Houston
7. Brenda Jensen
8. Patricia Kienle
9. William Mixon
10. John Musil
11. Alan Parr
12. Abby Roth
13. Robert Shrewsbury
14. Connie Sullivan
15. James Wagner

Unable to Attend
Gigi Davidson (Chair), David Newton, Brenda Yuzdepski

Government Liaisons
Jane Axelrad, FDA (via WebEx); Jonathan Bray, FDA; Ian Deveau, FDA; Susan Homire, FDA; John Metcalfe, FDA; Erika Pfeiler, FDA; Sara Rothman, FDA

Observers
Mark Compo, Veltek Associates, Inc.; Keith St. John, Wolters Kluwer; Mohamed Sarg, Johns Hopkins, on rotation with the American Society of Health-System Pharmacists

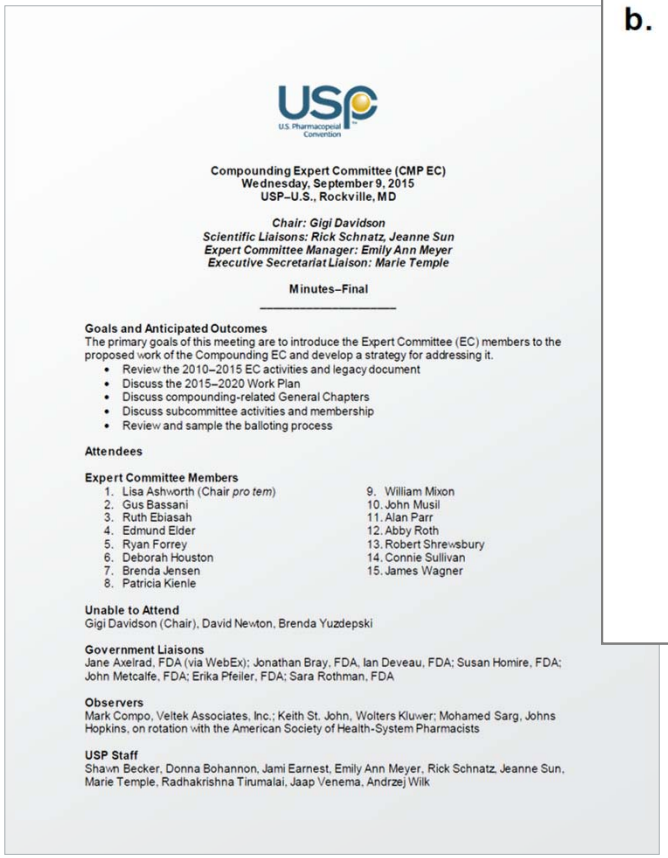
USP Staff
Shawn Becker, Donna Bohannon, Jami Earnest, Emily Ann Meyer, Rick Schnatz, Jeanne Sun, Marie Temple, Radhakrishna Tirumalai, Jaap Venema, Andrzej Wilk

c. U.S. Food and Drug Administration (FDA) Introduction
Ms. Jane Axelrad, the FDA lead on compounding, explained that 90 FDA liaisons serve on 24 USP ECs. As a result of the 2012 New England Compounding Center (NECC) fungal meningitis outbreak, FDA expanded its participation on the CMP EC, specifically on the subcommittee working on General Chapter <797> *Pharmaceutical Compounding–Sterile Preparations* Subcommittee. <797> is critically important for the safe compounding of sterile preparations as regulated by the federal government and the states. FDA is making the CMP EC a priority in this cycle and is expanding its participation by adding two FDA liaisons to identify cross-cutting policy issues that affect multiple subcommittees. Ms. Edisa Gozun will be the CMP EC's central point of contact.

- Over time, Ms. Axelrad gained more influence in the Chapter <795> and <797> Subcommittees, and ***her amplified role curiously coincided with FDA's increased focus on the CEC***.

Source Document: Compounding Expert Committee Meeting Minutes (Sept. 9, 2015), at p.3.

Case Study: Jane Axelrad's Secretive Dealings with USP



USP
U.S. Pharmacopeial Convention

Compounding Expert Committee (CMP EC)
Wednesday, September 9, 2015
USP–U.S., Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Rick Schnatz, Jeanne Sun
Expert Committee Manager: Emily Ann Meyer
Executive Secretariat Liaison: Marie Temple

Minutes–Final

Goals and Anticipated Outcomes
The primary goals of this meeting are to introduce the Expert Committee (EC) members to the proposed work of the Compounding EC and develop a strategy for addressing it.

- Review the 2010–2015 EC activities and legacy document
- Discuss the 2015–2020 Work Plan
- Discuss compounding-related General Chapters
- Discuss subcommittee activities and membership
- Review and sample the balloting process

Attendees

Expert Committee Members

1. Lisa Ashworth (Chair *pro tem*)
2. Gus Bassani
3. Ruth Ebiasah
4. Edmund Elder
5. Ryan Forrey
6. Deborah Houston
7. Brenda Jensen
8. Patricia Kienle
9. William Mixon
10. John Musil
11. Alan Parr
12. Abby Roth
13. Robert Shrewsbury
14. Connie Sullivan
15. James Wagner

Unable to Attend
Gigi Davidson (Chair), David Newton, Brenda Yuzdepski

Government Liaisons
Jane Axelrad, FDA (via WebEx); Jonathan Bray, FDA; Ian Deveau, FDA; Susan Homire, FDA; John Metcalfe, FDA; Erika Pfeiler, FDA; Sara Rothman, FDA

Observers
Mark Compo, Veltek Associates, Inc.; Keith St. John, Wolters Kluwer; Mohamed Sarg, Johns Hopkins, on rotation with the American Society of Health-System Pharmacists

USP Staff
Shawn Becker, Donna Bohannon, Jami Earnest, Emily Ann Meyer, Rick Schnatz, Jeanne Sun, Marie Temple, Radhakrishna Tirumalai, Jaap Venema, Andrzej Wilk

b. Creation of Subcommittees

Dr. Sun reported that EC members and FDA liaisons volunteered to serve on EC Subcommittees as follows:

1) <795> Pharmaceutical Compounding–Nonsterile Preparations

Chair: Bob Shrewsbury

EC Members: Gus Bassani, Gigi Davidson, John Musil, David Newton, Alan Parr, Brenda Yuzdepski

FDA Liaisons: Jane Axelrad, Jonathan Bray, Ian Deveau , Susan Homire, John Metcalfe, Erika Pfeiler

2) <797> Pharmaceutical Compounding–Sterile Preparations

Chair: Gigi Davidson

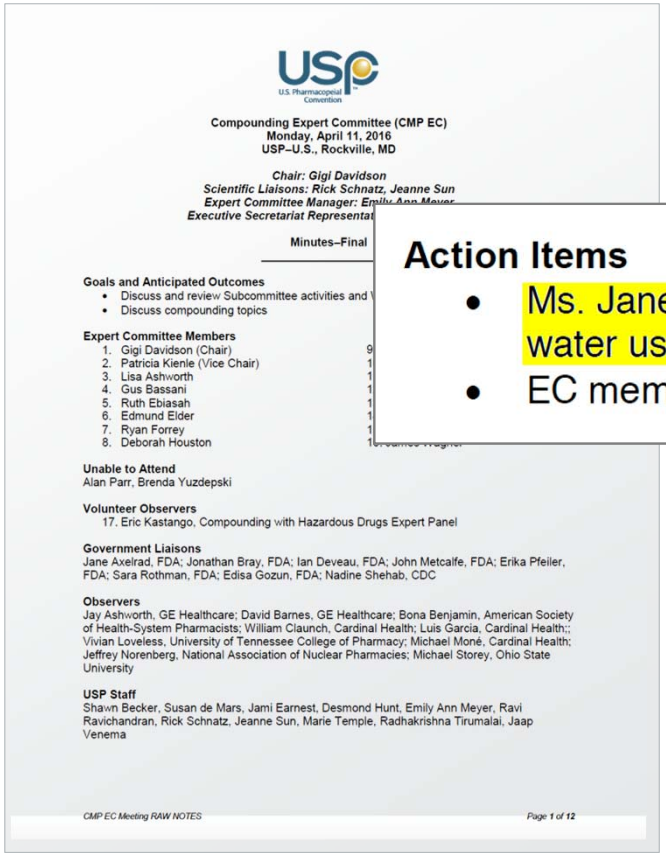
EC Members: Deb Houston, Patti Kienle, Bill Mixon, Dave Newton, Abby Roth, Connie Sullivan, Jim Wagner

FDA Liaisons: Jane Axelrad, Jonathan Bray, Ian Deveau, Susan Homire, John Metcalfe, Erika Pfeiler

- For the 2015-2020 cycle, Ms. Axelrad became an official FDA Liaison to the Chapter <795> and <797> Subcommittees.

Source Document: Compounding Expert Committee Meeting Minutes (Sept. 9, 2015), at p.12.

Case Study: Jane Axelrad's Secretive Dealings with USP



Compounding Expert Committee (CMP EC)
Monday, April 11, 2016
USP–U.S., Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Rick Schnatz, Jeanne Sun
Expert Committee Manager: Emily Ann Meyer
Executive Secretariat Representat

Minutes–Final

Goals and Anticipated Outcomes
- Discuss and review Subcommittee activities and
- Discuss compounding topics

Expert Committee Members
1. Gigi Davidson (Chair)
2. Patricia Kienle (Vice Chair)
3. Lisa Ashworth
4. Gus Bassani
5. Ruth Ebiasah
6. Edmund Elder
7. Ryan Forrey
8. Deborah Houston

Unable to Attend
Alan Parr, Brenda Yuzdepski

Volunteer Observers
17. Eric Kastango, Compounding with Hazardous Drugs Expert Panel

Government Liaisons
Jane Axelrad, FDA; Jonathan Bray, FDA; Ian Deveau, FDA; John Metcalfe, FDA; Erika Pfeiler, FDA; Sara Rothman, FDA; Edisa Gozun, FDA; Nadine Shehab, CDC

Observers
Jay Ashworth, GE Healthcare; David Barnes, GE Healthcare; Bona Benjamin, American Society of Health-System Pharmacists; William Claunch, Cardinal Health; Luis Garcia, Cardinal Health;; Vivian Loveless, University of Tennessee College of Pharmacy; Michael Moné, Cardinal Health; Jeffrey Norenberg, National Association of Nuclear Pharmacies; Michael Storey, Ohio State University

USP Staff
Shawn Becker, Susan de Mars, Jami Earnest, Desmond Hunt, Emily Ann Meyer, Ravi Ravichandran, Rick Schnatz, Jeanne Sun, Marie Temple, Radhakrishna Tirumalai, Jaap Venema

CMP EC Meeting RAW NOTES *Page 1 of 12*

Action Items

- Ms. Jane Axelrad will work with FDA colleagues to explore product labeling related to water used for reconstitution of nonsterile products and send an update to the EC.
- EC members will send comments on proposed <795> revisions to Dr. Shrewsbury.

- USP dispatched Ms. Axelrad to liaise directly with her "FDA colleagues" in order obtain ***information relevant to Chapter <795>*** from FDA and to report back to the CEC.

Source Document: Compounding Expert Committee Meeting Minutes (April 11, 2016), at p.8.

Case Study: Jane Axelrad's Secretive Dealings with USP

THE HILL

Congress, prevent another outbreak — Don't roll back drug contamination protections

BY JANE AXELRAD, OPINION CONTRIBUTOR - 07/10/17 09:20 AM EDT

Just In...

Yovanovitch calls for investigation following evidence released by lawmakers
ADMINISTRATION -- 9M 14S AGO

Video emerges of Sanders saying in 1988 a woman could be elected president
CAMPAIGN -- 11M 48S AGO

Steyer calls for cuts to defense spending
CAMPAIGN -- 11M 50S AGO

Biden, Sanders tangle on Iraq vote
CAMPAIGN -- 17M 1S AGO

Trump touts killing of 'son of a b----' Soleimani
ADMINISTRATION -- 42M 58S AGO

Flynn moves to withdraw guilty plea ahead of sentencing
REGULATION -- 43M 22S AGO

Tennessee lawmakers pass bill allowing adoption agencies to refuse to place children with same-sex couples
STATE WATCH -- 52M 19S AGO

Trump: 'I don't believe' Sanders said a woman can't win the presidency
CAMPAIGN -- 59M 33S AGO

VIEW ALL

56 SHARES

SHARE TW

© Getty Images

In September 2012, contaminated medications distributed by a state-licensed compounding pharmacy, the New England Compounding Center, caused a fungal meningitis outbreak that killed more than 70 people and injured 750 in 20 states. States hardest hit were Michigan (264 patients), Tennessee (153), Indiana (93), Virginia (56), Florida (25) and Ohio (20).

On June 26, Barry Cadden, the owner of the New England Compounding Center, was sentenced to nine years in prison for crimes he committed related to the outbreak.

In 2013, Congress enacted bipartisan legislation to prevent such an outbreak from happening again. Now, after heavy lobbying from pharmacies and practitioners who are losing lucrative business because of those protections, the Agriculture Subcommittee of the House Appropriations Committee this week included report language and Congress is considering legislation that would gut the law and place patients at risk.

Compounding is the process of combining, mixing or altering drug ingredients to create a new medication. Compounded drugs are not FDA-approved. They are supposed to be customized to meet an individual

When it enacted the CQA in 2013, Congress created the new voluntary category of outsourcing facilities. Instead of requiring compounders that want to supply compounded drugs without obtaining prescriptions to become outsourcing facilities and adhere to higher standards, Congress decided to rely on market forces to encourage pharmacies to adopt this business model. More than 70 facilities have voluntarily registered with FDA as outsourcing facilities, providing millions of units of medications to healthcare facilities, doctors offices, and clinics. If Congress eliminates the prescription requirement, it would remove any incentive for compounders to register as outsourcing facilities and comply with the standards that are necessary for the safety of higher volume, non-individualized compounding.

- While serving as an FDA Government Liaison to the CEC, Ms. Axelrad retired from the FDA in April 2016 after 25 years of service.
- Ms. Axelrad then launched a consulting firm called Axelrad Solutions, LLC and started calling for changes of law and ***tighter restrictions against the entire compounding industry***.

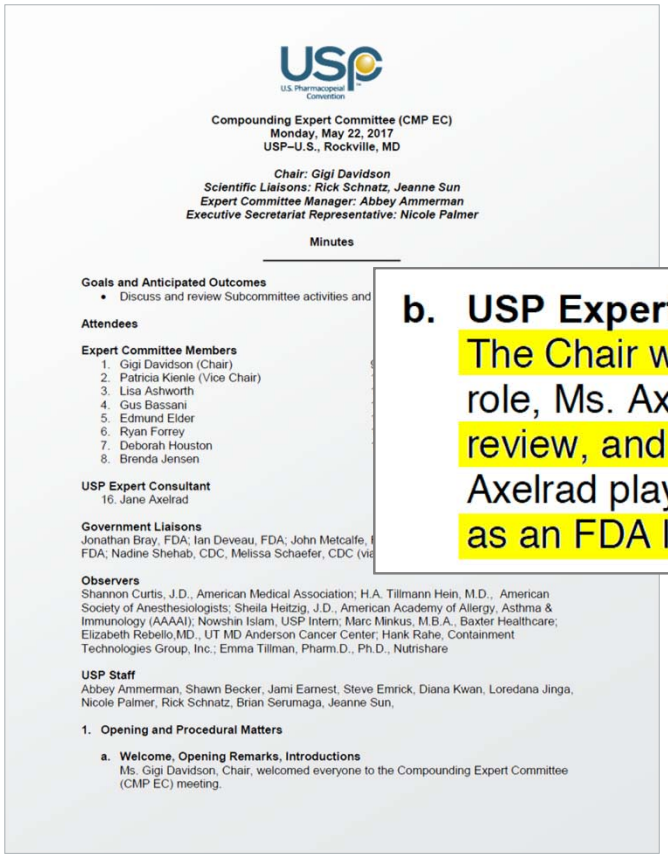
Source Document: Jane Axelrad, *Congress, prevent another outbreak – Don't roll back drug contamination protections*, The Hill (July 10, 2017).

Case Study: Jane Axelrad's Secretive Dealings with USP

- In May 2017, USP hires a new "USP Expert Consultant" to finalize the <797> and <795> revisions:

Jane Axelrad

Case Study: Jane Axelrad's Secretive Dealings with USP



USP
U.S. Pharmacopeial Convention

Compounding Expert Committee (CMP EC)
Monday, May 22, 2017
USP–U.S., Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Rick Schnatz, Jeanne Sun
Expert Committee Manager: Abbey Ammerman
Executive Secretariat Representative: Nicole Palmer

Minutes

Goals and Anticipated Outcomes
- Discuss and review Subcommittee activities and

Attendees

Expert Committee Members
1. Gigi Davidson (Chair)
2. Patricia Kienle (Vice Chair)
3. Lisa Ashworth
4. Gus Bassani
5. Edmund Elder
6. Ryan Forrey
7. Deborah Houston
8. Brenda Jensen

USP Expert Consultant
16. Jane Axelrad

Government Liaisons
Jonathan Bray, FDA; Ian Deveau, FDA; John Metcalfe,
FDA; Nadine Shehab, CDC, Melissa Schaefer, CDC (vi

Observers
Shannon Curtis, J.D., American Medical Association; H.A. Tillmann Hein, M.D., American Society of Anesthesiologists; Sheila Heitzig, J.D., American Academy of Allergy, Asthma & Immunology (AAAAI); Nowshin Islam, USP Intern; Marc Minkus, M.B.A., Baxter Healthcare; Elizabeth Rebello,MD., UT MD Anderson Cancer Center; Hank Rahe, Containment Technologies Group, Inc.; Emma Tillman, Pharm.D., Ph.D., Nutrishare

USP Staff
Abbey Ammerman, Shawn Becker, Jami Earnest, Steve Emrick, Diana Kwan, Loredana Jinga, Nicole Palmer, Rick Schnatz, Brian Serumaga, Jeanne Sun,

1. **Opening and Procedural Matters**

   a. **Welcome, Opening Remarks, Introductions**
   Ms. Gigi Davidson, Chair, welcomed everyone to the Compounding Expert Committee (CMP EC) meeting.

b. USP Expert Consultant

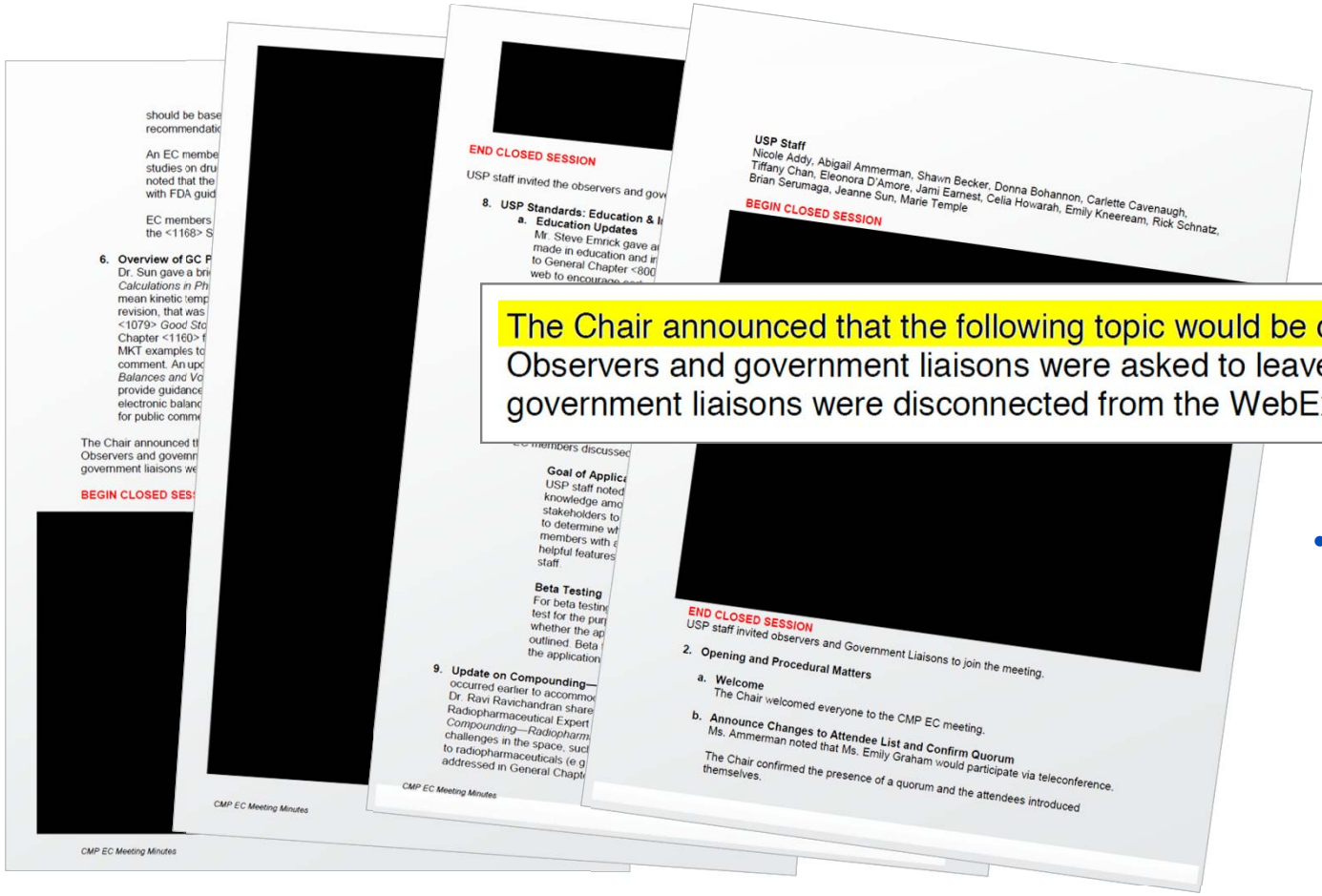
The Chair welcomed Jane Axelrad in her new role as USP Expert Consultant. In this role, Ms. Axelrad will serve as a volunteer, participate in discussion and document review, and provide expertise not otherwise represented in the EC membership. Ms. Axelrad played a key role in assisting the CMP EC in revising <797> during her work as an FDA liaison.

Source Document: Compounding Expert Committee Meeting Minutes (May 22, 2017), at p.3.

Case Study: Jane Axelrad's Secretive Dealings with USP

- Other than announcing her new role, ***USP's meeting minutes do not reflect any discussion of the propriety of Ms. Axelrad's new position***, nor do they show any votes/approvals of the new "expert consultant" position.
- Nor is it clear whether Ms. Axelrad had voting power or whether she was actually a formal member of the CEC.
- USP evidently saw no impediment to Ms. Axelrad acting on behalf of USP despite acknowledging her "***key role***" in assisting the Chapter <797> revisions as a representative of FDA.

Case Study: Jane Axelrad's Secretive Dealings with USP



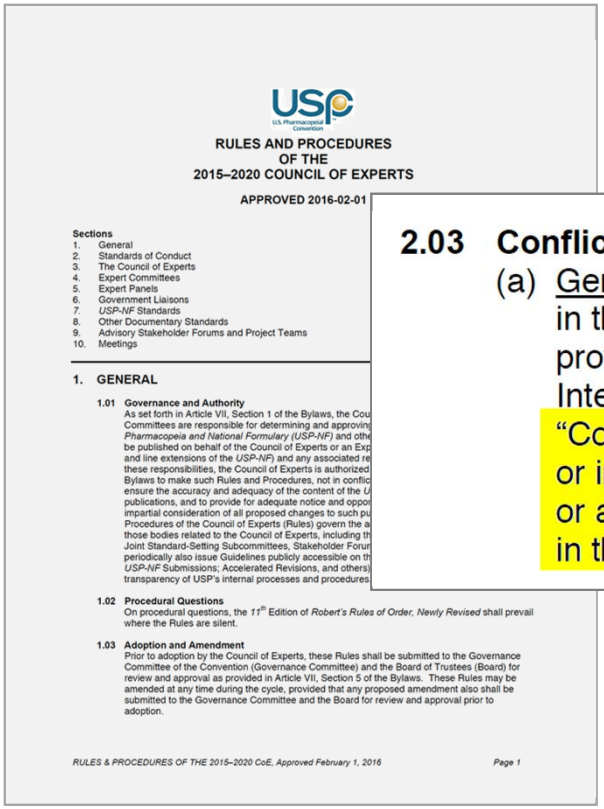
The Chair announced that the following topic would be discussed in a closed session. Observers and government liaisons were asked to leave the meeting room. Observers and government liaisons were disconnected from the WebEx.

- ***After Ms. Axelrad arrived*** as USP's "Expert Consultant," the CEC returned to holding ***closed sessions.***

Source Document: Compounding Expert Committee Meeting Minutes (Sept. 29, 2017), at p.2-6; Compounding Expert Committee Meeting Minutes (April 11, 2018), at p.2-3.

Problems with USP's Development of the Revised Chapters: *Conflicts of Interest Infected the Process*

USP's Definition of "Conflict of Interest"



RULES AND PROCEDURES
OF THE
2015–2020 COUNCIL OF EXPERTS

APPROVED 2016-02-01

Sections
1. General
2. Standards of Conduct
3. The Council of Experts
4. Expert Committees
5. Expert Panels
6. Government Liaisons
7. *USP-NF* Standards
8. Other Documentary Standards
9. Advisory Stakeholder Forums and Project Teams
10. Meetings

1. GENERAL

1.01 Governance and Authority
As set forth in Article VII, Section 1 of the Bylaws, the Cou
Committees are responsible for determining and approvin
Pharmacopeia and National Formulary (USP-NF) and othe
be published on behalf of the Council of Experts or an Exp
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these responsibilities, the Council of Experts is authorized
Bylaws to make such Rules and Procedures, not in conflic
ensure the accuracy and adequacy of the content of the U
publications, and to provide for adequate notice and oppor
impartial consideration of all proposed changes to such pu
Procedures of the Council of Experts (Rules) govern the a
those bodies related to the Council of Experts, including th
Joint Standard-Setting Subcommittees, Stakeholder Forur
periodically also issue Guidelines publicly accessible on th
USP-NF Submissions; Accelerated Revisions, and others)
transparency of USP's internal processes and procedures.

1.02 Procedural Questions
On procedural questions, the 11th Edition of *Robert's Rules of Order, Newly Revised* shall prevail where the Rules are silent.

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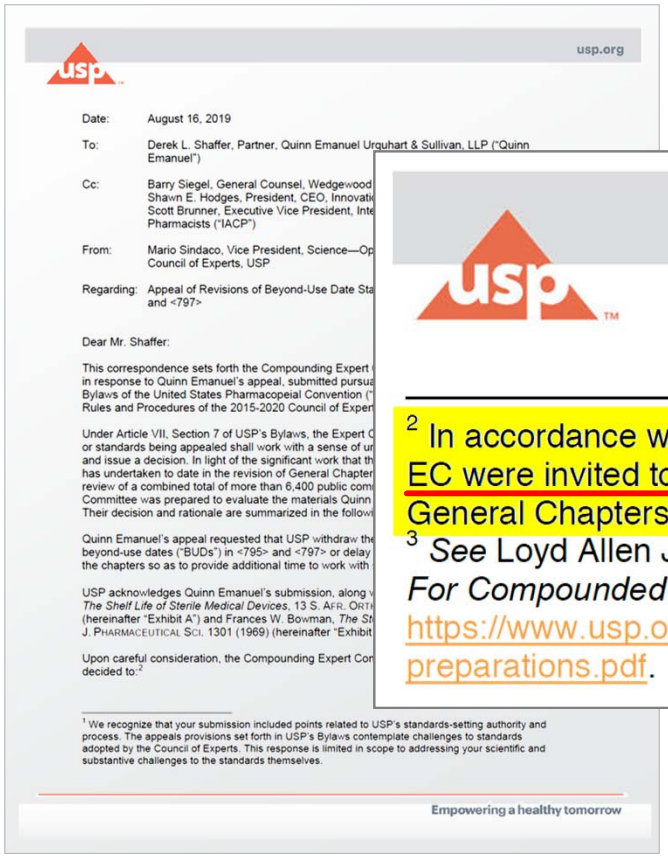
RULES & PROCEDURES OF THE 2015–2020 CoE, Approved February 1, 2016 *Page 1*

2.03 Conflict of Interest

(a) General. Pursuant to Article VIII, Section 1, of the Bylaws and the Conflicts of Interest Policy in the Code of Ethics, all CoE/EC Expert members shall adhere to the Conflicts of Interest provisions set forth in this section. Expert Panel members are subject to the Conflict of Interest requirements contained in Section 5.05(a) of these Rules. As used in these Rules, "Conflict of Interest" includes, but is not limited to, any matter in which an Expert has a direct or indirect financial interest or any other personal interest of any kind which would preclude or appear to preclude such individual from exercising impartial judgment or otherwise acting in the best interest of USP.

USP Belatedly Discloses that Certain Unidentified CEC Members Had Conflicts of Interest



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Date: August 16, 2019

To: Derek L. Shaffer, Partner, Quinn Emanuel Urquhart & Sullivan, LLP ("Quinn Emanuel")

Cc: Barry Siegel, General Counsel, Wedgewood
Shawn E. Hodges, President, CEO, Innovati
Scott Brunner, Executive Vice President, Inte
Pharmacists ("IACP")

From: Mario Sindaco, Vice President, Science—Op
Council of Experts, USP

Regarding: Appeal of Revisions of Beyond-Use Date Sta
and <797>

Dear Mr. Shaffer:

This correspondence sets forth the Compounding Expert
in response to Quinn Emanuel's appeal, submitted pursua
Bylaws of the United States Pharmacopeial Convention ("
Rules and Procedures of the 2015-2020 Council of Exper

Under Article VII, Section 7 of USP's Bylaws, the Expert C
or standards being appealed shall work with a sense of ur
and issue a decision. In light of the significant work that th
has undertaken to date in the revision of General Chapter
review of a combined total of more than 6,400 public com
Committee was prepared to evaluate the materials Quinn
Their decision and rationale are summarized in the follow

Quinn Emanuel's appeal requested that USP withdraw the
beyond-use dates ("BUDs") in <795> and <797> or delay
the chapters so as to provide additional time to work with

USP acknowledges Quinn Emanuel's submission, along v
The Shelf Life of Sterile Medical Devices, 13 S. AFR. ORTH
(hereinafter "Exhibit A") and Frances W. Bowman, *The St*
J. PHARMACEUTICAL SCI. 1301 (1969) (hereinafter "Exhibit

Upon careful consideration, the Compounding Expert Cor
decided to:[2]

[1] We recognize that your submission included points related to USP's standards-setting authority and process. The appeals provisions set forth in USP's Bylaws contemplate challenges to standards adopted by the Council of Experts. This response is limited in scope to addressing your scientific and substantive challenges to the standards themselves.

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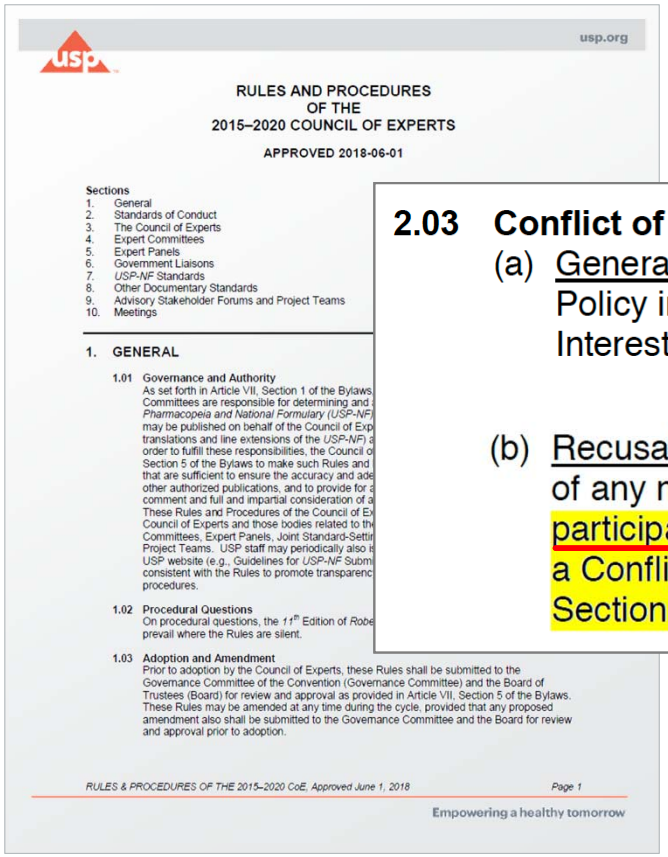
* * *

[2] In accordance with USP's rules and policies regarding conflicts of interest, all members of the CMP EC were invited to discuss the appeal. However, members with conflicts of interest related to the General Chapters under appeal recused themselves prior to final discussion and voting.

[3] *See* Loyd Allen Jr, Gus S Bassani, Edmund J Elder Jr, and Alan F Parr, *Strength And Stability Testing For Compounded Preparations*, U.S. PHARMACOPEIAL CONVENTION (Jan. 13, 2014), https://www.usp.org/sites/default/files/usp/document/FAQs/strength-stability-testing-compounded-preparations.pdf.

Source Document: Letter from Mario Sindaco to Derek Shaffer (Aug. 16, 2019).

Conflicted CEC Members Participated in the Development of the New Standards



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RULES AND PROCEDURES
OF THE
2015–2020 COUNCIL OF EXPERTS

APPROVED 2018-06-01

Sections
1. General
2. Standards of Conduct
3. The Council of Experts
4. Expert Committees
5. Expert Panels
6. Government Liaisons
7. *USP-NF* Standards
8. Other Documentary Standards
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RULES & PROCEDURES OF THE 2015–2020 CoE, Approved June 1, 2018 Page 1

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2.03 Conflict of Interest

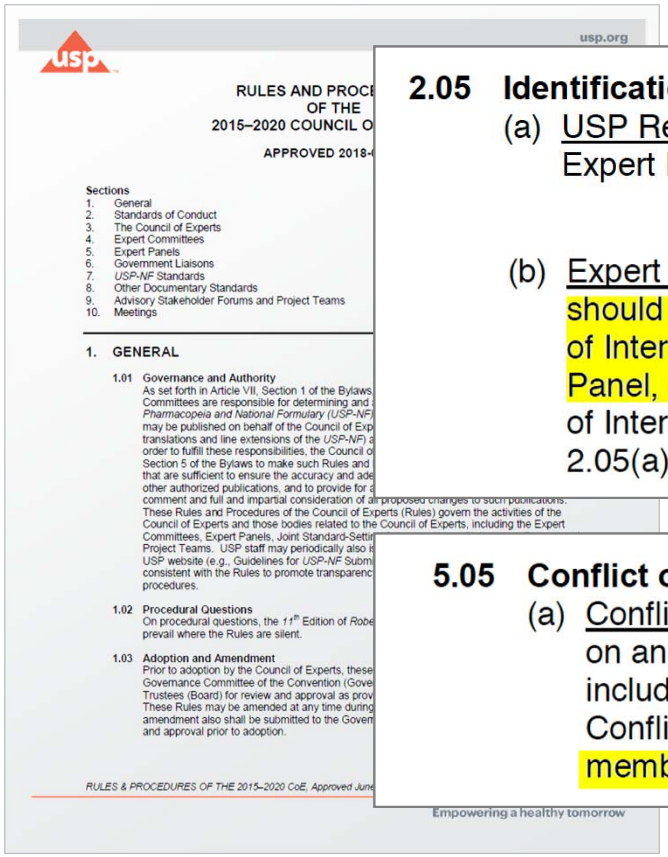
(a) General. Pursuant to Article VIII, Section 1, of the Bylaws and the Conflicts of Interest Policy in the Code of Ethics, all CoE/EC Expert members shall adhere to the Conflicts of Interest provisions set forth in this section. Expert Panel members are subject to the

* * *

(b) Recusal. No CoE/EC Expert shall vote nor take part in the final discussion or deliberation of any matter in which he or she has a Conflict of Interest. An Expert Panel member may participate in deliberations or recommendations regarding matters in which he or she has a Conflict of Interest provided disclosure of a Conflict of Interest is made pursuant to Section 5.05(a) of these Rules.

Source Document: Rules and Procedures of the 2015-2020 USP Council of Experts (approved 06/01/2018), Sec. 2.03.

Disclosure of Conflicts Is Limited to USP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RULES AND PROCE
OF THE
2015–2020 COUNCIL O

APPROVED 2018-

Sections
1. General
2. Standards of Conduct
3. The Council of Experts
4. Expert Committees
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6. Government Liaisons
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RULES & PROCEDURES OF THE 2015–2020 CoE, Approved Jun

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2.05 Identification and Resolution of Conflict Issues.

(a) USP Responsibility. USP staff, together with the chairperson of an Expert Committee or Expert Panel shall review Disclosure Statements on a periodic basis identify potential

* * *

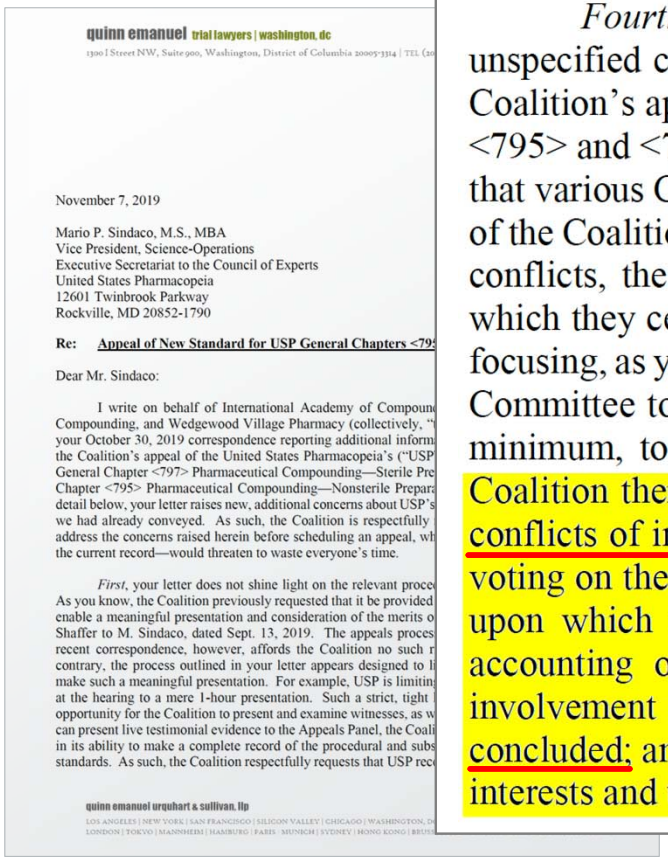
(b) Expert Responsibility. Any CoE/EC Expert or Expert Panel member who believes or should have reason to believe that he or she may have an apparent or potential Conflict of Interest shall notify USP staff and the chairperson of the Expert Committee or Expert Panel, as applicable, prior to any work on or discussion of the matter in question. Conflict of Interest issues identified by a CoE/EC Expert shall be resolved as described in Section 2.05(a) above.

5.05 Conflict of Interest and Confidentiality.

(a) Conflicts. Conflicts of Interest, as defined in Section 2.03(a), will not be a bar to participation on an Expert Panel or in any deliberations or recommendations of the Expert Panel, including voting, provided the Expert Panel member timely and adequately discloses any Conflict of Interest as required by Sections 2.03, 2.04 and 2.05 of these Rules to other members of the Expert Panel including the chairperson.

Source Document: Rules and Procedures of the 2015-2020 USP Council of Experts (approved 06/01/2018), Sec. 2.05; 5.05.

The Coalition Requests Basic Information About these Conflicts



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1300 I Street NW, Suite 900, Washington, District of Columbia 20005-3314 | TEL (20

November 7, 2019

Mario P. Sindaco, M.S., MBA
Vice President, Science-Operations
Executive Secretariat to the Council of Experts
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Appeal of New Standard for USP General Chapters <79

Dear Mr. Sindaco:

I write on behalf of International Academy of Compoun
Compounding, and Wedgewood Village Pharmacy (collectively, "
your October 30, 2019 correspondence reporting additional inform
the Coalition's appeal of the United States Pharmacopeia's ("USP
General Chapter <797> Pharmaceutical Compounding—Sterile Pre
Chapter <795> Pharmaceutical Compounding—Nonsterile Prepara
detail below, your letter raises new, additional concerns about USP's
we had already conveyed. As such, the Coalition is respectfully
address the concerns raised herein before scheduling an appeal, wh
the current record—would threaten to waste everyone's time.

First, your letter does not shine light on the relevant proce
As you know, the Coalition previously requested that it be provided
enable a meaningful presentation and consideration of the merits o
Shaffer to M. Sindaco, dated Sept. 13, 2019. The appeals proces
recent correspondence, however, affords the Coalition no such r
contrary, the process outlined in your letter appears designed to l
make such a meaningful presentation. For example, USP is limitin
at the hearing to a mere 1-hour presentation. Such a strict, tight
opportunity for the Coalition to present and examine witnesses, as w
can present live testimonial evidence to the Appeals Panel, the Coali
in its ability to make a complete record of the procedural and subs
standards. As such, the Coalition respectfully requests that USP rec

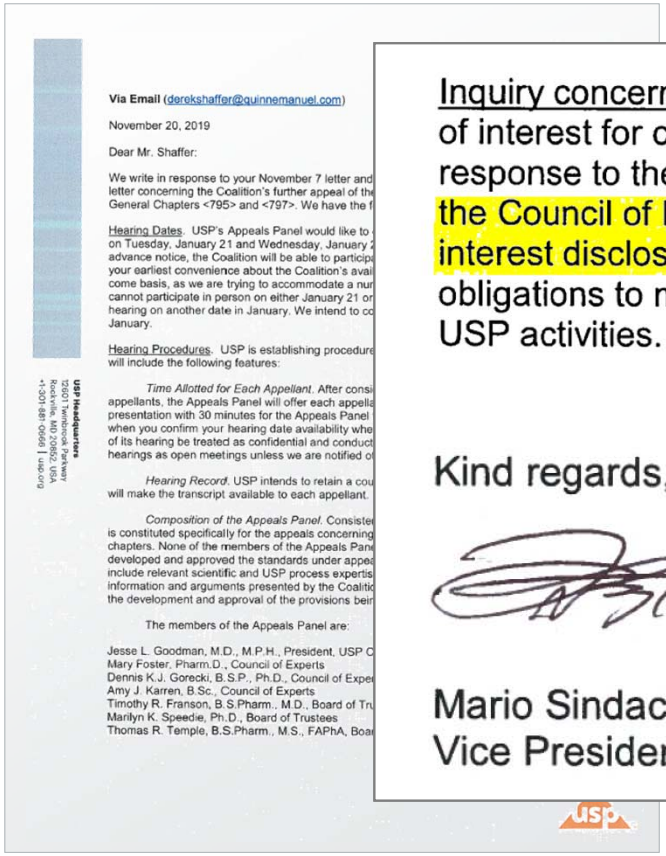
quinn emanuel urquhart & sullivan, llp

LOS ANGELES | NEW YORK | SAN FRANCISCO | SILICON VALLEY | CHICAGO | WASHINGTON, D
LONDON | TOKYO | MANNHEIM | HAMBURG | PARIS | MUNICH | SYDNEY | HONG KONG | BRUS

Fourth, the Coalition also requests additional information from USP concerning the unspecified conflicts of interests USP acknowledged in its August 16, 2019 initial denial of the Coalition's appeal. *See* Appeal of Revisions of Beyond-Use Date Standards in General Chapters <795> and <797>, dated Aug. 16, 2019 at 2, fn. 2. In particular, USP acknowledged in that letter that various CEC members had conflicts of interest yet participated in the discussion of the merits of the Coalition's appeal. To date, USP has not provided any information about the nature of these conflicts, the conflicted members, their involvement in the Coalition's appeal, or the dates on which they ceased further participation in the new standards. To the extent the Appeals Panel is focusing, as you write, on addressing "the sufficiency of the process used by the responsible Expert Committee to develop and approve the standards under appeal," it is incumbent upon USP, at a minimum, to provide information about these conflicts well in advance of any hearing. The Coalition therefore respectfully requests that USP promptly (i) identify all CMC members with conflicts of interests who may or may not have recused themselves prior to final discussion and voting on the new standards; (ii) the precise nature of those conflicts of interests; (iii) the date(s) upon which those conflicts of interests were disclosed to USP and/or the CMC; (iv) a full accounting of the conflicted members' involvement in the Coalition's appeal and/or their involvement in the creation of the new standards; (v) the dates on which their participation concluded; and (vi) all internal USP documents and communications concerning these conflicts of interests and the conflicted members.

Source Document: Letter from Derek Shaffer to Mario Sindaco (Nov. 7, 2019).

USP Refuses to Provide Information Related to these Conflicts



Via Email (derekshaffer@quinnemanuel.com)

November 20, 2019

Dear Mr. Shaffer:

We write in response to your November 7 letter and
letter concerning the Coalition's further appeal of the
General Chapters <795> and <797>. We have the f

Hearing Dates. USP's Appeals Panel would like to
on Tuesday, January 21 and Wednesday, January
advance notice, the Coalition will be able to particip
your earliest convenience about the Coalition's avai
come basis, as we are trying to accommodate a nur
cannot participate in person on either January 21 or
hearing on another date in January. We intend to co
January.

Hearing Procedures. USP is establishing procedure
will include the following features:

Time Allotted for Each Appellant. After consi
appellants, the Appeals Panel will offer each appella
presentation with 30 minutes for the Appeals Panel
when you confirm your hearing date availability whe
of its hearing be treated as confidential and conduct
hearings as open meetings unless we are notified o

Hearing Record. USP intends to retain a cou
will make the transcript available to each appellant.

Composition of the Appeals Panel. Consiste
is constituted specifically for the appeals concerning
chapters. None of the members of the Appeals Pan
developed and approved the standards under appe
include relevant scientific and USP process expertis
information and arguments presented by the Coaliti
the development and approval of the provisions beir

The members of the Appeals Panel are:

Jesse L. Goodman, M.D., M.P.H., President, USP C
Mary Foster, Pharm.D., Council of Experts
Dennis K.J. Gorecki, B.S.P., Ph.D., Council of Expe
Amy J. Karren, B.Sc., Council of Experts
Timothy R. Franson, B.S.Pharm., M.D., Board of Tru
Marilyn K. Speedie, Ph.D., Board of Trustees
Thomas R. Temple, B.S.Pharm., M.S., FAPhA, Boa

USP Headquarters
12601 Twinbrook Parkway
Rockville, MD 20852, USA
+1 301 881 0666 | usp.org

Inquiry concerning Conflicts of Interest. The Coalition requests information concerning conflicts of interest for certain Expert Committee members, as referenced in a footnote of our August 16 response to the Coalition's first-level appeal. Under Section 2 of the Rules and Procedures of the Council of Experts, USP is required to maintain confidentiality relating to the conflict-of-interest disclosures of its Expert Committee and Expert Panel members, who themselves have obligations to maintain confidentiality of information gained in the course of their participation in USP activities.

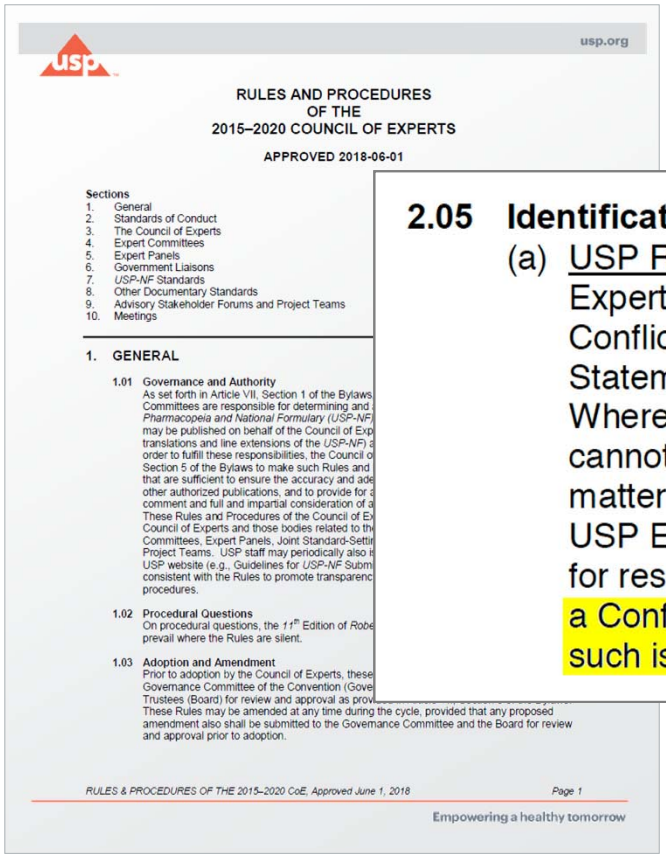
* * *

Kind regards,

Mario Sindaco
Vice President, Science—Operations and Executive Secretariat, Council of Experts

Source Document: Letter from Mario Sindaco to Derek Shaffer (Nov. 20, 2019).

Section 2 of the Rules & Procedures Does Not Prevent Disclosure



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RULES AND PROCEDURES
OF THE
2015–2020 COUNCIL OF EXPERTS

APPROVED 2018-06-01

Sections

1. General
2. Standards of Conduct
3. The Council of Experts
4. Expert Committees
5. Expert Panels
6. Government Liaisons
7. *USP-NF* Standards
8. Other Documentary Standards
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amendment also shall be submitted to the Governance Committee and the Board for review
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RULES & PROCEDURES OF THE 2015–2020 CoE, Approved June 1, 2018 Page 1

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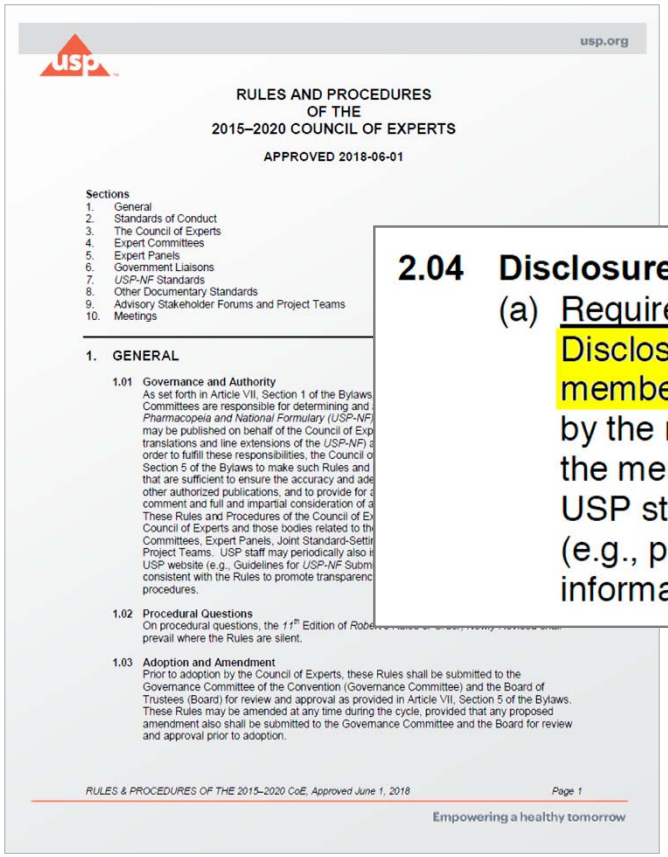
2.05 Identification and Resolution of Conflict Issues.

(a) USP Responsibility. USP staff, together with the chairperson of an Expert Committee or Expert Panel shall review Disclosure Statements on a periodic basis identify potential Conflicts of Interest and to ensure that all interests disclosed on the Disclosure Statements are disclosed to the other members of the Expert Committee or Expert Panel. Where an apparent or potential Conflict of Interest is identified by a CoE/EC Expert and cannot be resolved through voluntary recusal and/or intervention by the EC chair, the matter shall be referred to the Chair of the Council of Experts (CoE Chairperson) and the USP Executive Secretariat for resolution. The CoE Chairperson shall have final authority for resolving matters involving Conflicts of Interest. The minutes of any meeting at which a Conflict of Interest issue has been identified shall reflect disclosure and resolution of such issue, including any recusal of a CoE/EC Expert due to Conflict of Interest.

Source Document: Rules and Procedures of the 2015-2020 USP Council of Experts (approved 06/01/2018), Sec. 2.05.

Section 2 of the Rules & Procedures Does Not Prevent Disclosure



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RULES AND PROCEDURES
OF THE
2015–2020 COUNCIL OF EXPERTS

APPROVED 2018-06-01

Sections
1. General
2. Standards of Conduct
3. The Council of Experts
4. Expert Committees
5. Expert Panels
6. Government Liaisons
7. *USP-NF* Standards
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RULES & PROCEDURES OF THE 2015–2020 CoE, Approved June 1, 2018 Page 1

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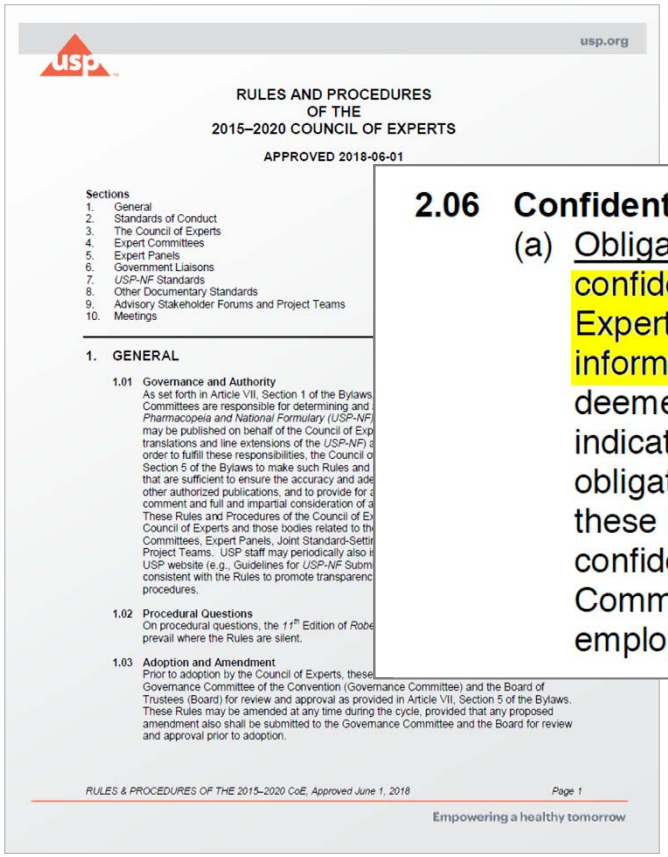
2.04 Disclosure Statements

(a) Requirement. Each COE/EC Expert and Expert Panel member shall submit to USP a Disclosure Statement disclosing all employment, professional research, organizational memberships, and other relevant interests. The Disclosure Statement, shall be updated by the member as necessary to keep it current or as requested periodically by USP, and the member is also obligated to advise the Expert Committee or Expert Panel chair and USP staff of changing or emerging interests. Except as specified in Section 2.05 below (e.g., periodic disclosure to fellow Expert Committee or Expert Panel members), the information provided in Disclosure Statements shall be kept confidential.

Source Document: Rules and Procedures of the 2015-2020 USP Council of Experts (approved 06/01/2018), Sec. 2.04.

Section 2 of the Rules & Procedures Does Not Prevent Disclosure



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OF THE
2015–2020 COUNCIL OF EXPERTS

APPROVED 2018-06-01

Sections
1. General
2. Standards of Conduct
3. The Council of Experts
4. Expert Committees
5. Expert Panels
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RULES & PROCEDURES OF THE 2015–2020 CoE, Approved June 1, 2018 Page 1

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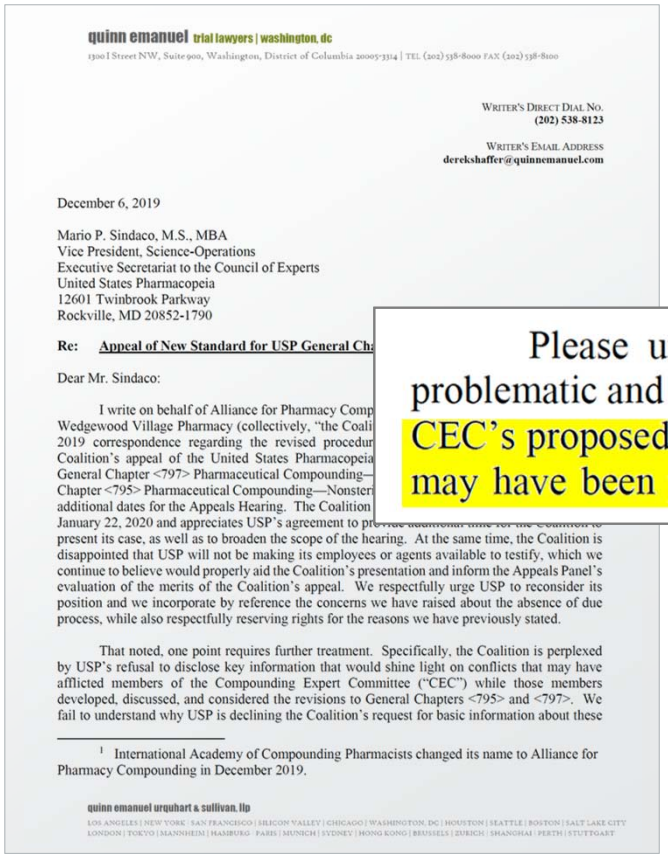
2.06 Confidentiality

(a) Obligation to Maintain Confidentiality. Each CoE/EC Expert member shall maintain the confidentiality of all information gained in the course of his or her activities as a CoE/EC Expert, and shall not use or disclose such information for any purpose, unless such information is already publicly available. In case of doubt as to whether information is deemed confidential, the information shall be treated as confidential until otherwise indicated by the USP Executive Secretariat or USP Secretary. Expert Panel members are obligated to maintain confidentiality of materials in accordance with Section 5.05(b) of these Rules. CoE/EC Experts and Expert Panel members should receive and send any confidential electronic communications (i.e. all communications in the case of Expert Committee members) from a private email address, not shared with or accessible to their employer or any other 3rd party.

Source Document: Rules and Procedures of the 2015-2020 USP Council of Experts (approved 06/01/2018), Sec. 2.06.

The Coalition Requests USP Reconsider Its Refusal to Provide Conflicts Information



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WRITER'S DIRECT DIAL NO.
(202) 538-8123

WRITER'S EMAIL ADDRESS
derekshaffer@quinnemanuel.com

December 6, 2019

Mario P. Sindaco, M.S., MBA
Vice President, Science-Operations
Executive Secretariat to the Council of Experts
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Appeal of New Standard for USP General Ch

Dear Mr. Sindaco:

I write on behalf of Alliance for Pharmacy Comp
Wedgewood Village Pharmacy (collectively, "the Coali
2019 correspondence regarding the revised procedur
Coalition's appeal of the United States Pharmacopeia
General Chapter <797> Pharmaceutical Compounding—
Chapter <795> Pharmaceutical Compounding—Nonster
additional dates for the Appeals Hearing. The Coalition
January 22, 2020 and appreciates USP's agreement to pr
present its case, as well as to broaden the scope of the hearing. At the same time, the Coalition is disappointed that USP will not be making its employees or agents available to testify, which we continue to believe would properly aid the Coalition's presentation and inform the Appeals Panel's evaluation of the merits of the Coalition's appeal. We respectfully urge USP to reconsider its position and we incorporate by reference the concerns we have raised about the absence of due process, while also respectfully reserving rights for the reasons we have previously stated.

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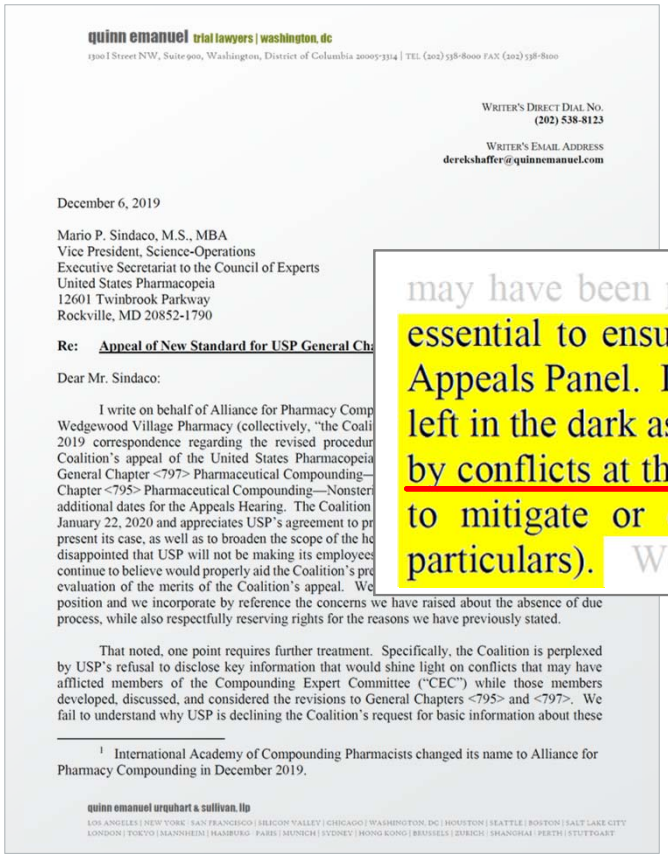
Please understand that USP's refusal to provide this information to the Coalition is problematic and concerning. For one, this information is critical to assessing the legitimacy of the CEC's proposed revisions to Chapters <795> and <797> and the extent to which these revisions may have been propelled by undisclosed, improper influences. Separately, this information is

The Coalition Requests USP Reconsider Its Refusal to Provide Conflicts Information



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WRITER'S EMAIL ADDRESS
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December 6, 2019

Mario P. Sindaco, M.S., MBA
Vice President, Science-Operations
Executive Secretariat to the Council of Experts
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Appeal of New Standard for USP General Ch

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may have been propelled by undisclosed, improper influences. Separately, this information is essential to ensuring that the Coalition receives a full and fair hearing before a duly informed Appeals Panel. Indeed, absent this information, the Coalition as well as the Appeals Panel will be left in the dark as to whether and to what extent the revisions under appeal may have been tainted by conflicts at the Expert Committee stage, and as to how, when, and to what extent USP sought to mitigate or obviate the conflicts it ultimately acknowledged (albeit while withholding particulars). We cannot conceive of a legitimate reason why USP would keep secret basic

Source Document: Letter from Derek Shaffer to Mario Sindaco (Dec. 6, 2019).

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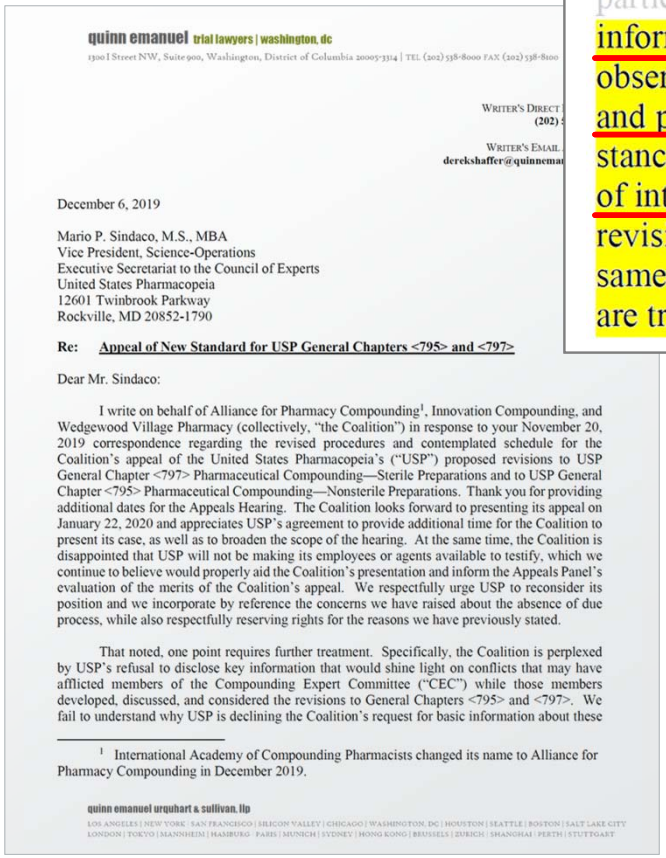

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particulars). We cannot conceive of a legitimate reason why USP would keep secret basic information that stands to benefit all interested parties—including appellants, stakeholders, public observers, and the Appeals Panel itself—about identified conflicts of interest that may bear directly and profoundly upon the revisions proposed by the Expert Committee. For USP to persist in its stance is to say, in essence, that certain members of the Expert Committee *did* in fact face conflicts of interest while working and deliberating on the revisions, potentially right up until the point the revisions were put to a vote, but that USP is sworn to cover up those conflicts and its handling of same so as to thwart full and fair examination of these particulars on appeal. Needless to say, we are troubled by that stance and believe others should be too.

"[The Coalition] cannot conceive of a legitimate reason ***why USP would keep secret basic information that stands to benefit all interested parties*** . . . about identified conflicts of interest that may ***bear directly and profoundly upon the revisions proposed by the Expert Committee***. For USP to persist in its stance is to say . . . that ***certain members of the Expert Committee did in fact face conflicts of interest while working and deliberating on the revisions*** . . . but that USP is sworn to cover up those conflicts and its handling of same so as to ***thwart full and fair examination of these particulars on appeal***."

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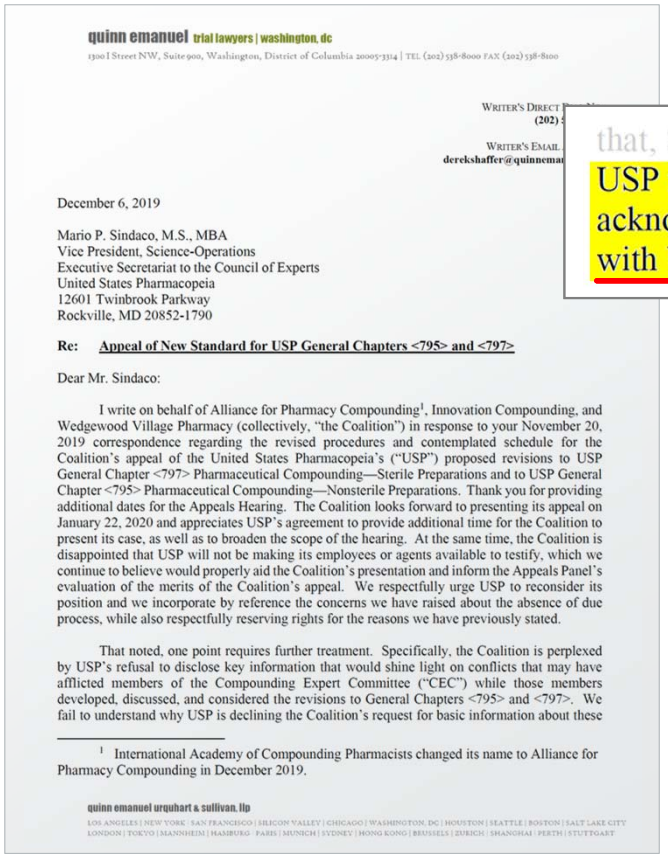

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that, Section 2.04 expressly yields to Section 2.05: "Except as specified in Section 2.05 . . . ." If USP is nonetheless claiming the ability to shield from external scrutiny its official handling of an acknowledged conflict and its minutes reflecting same, then something is seriously amiss not only with USP's reading of Section 2, but with its overall approach to conflicts and/or transparency.

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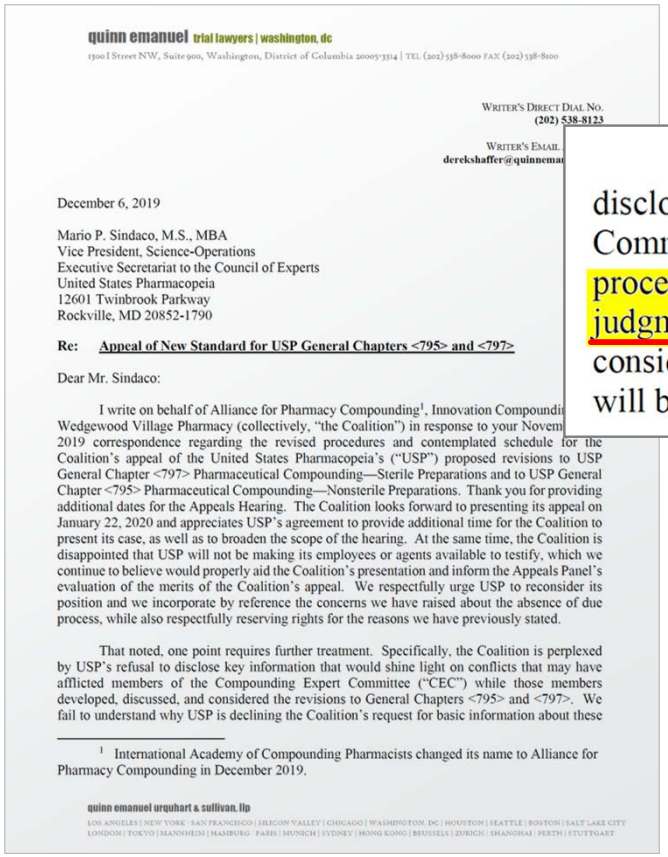

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In sum, nothing in USP's Rules (or Bylaws) disables, limits, or otherwise inhibits USP's disclosure of information about how it has addressed conflicts of interests among its Expert Committee. To the contrary, the Rules call for the disclosure of this information, and so does due process, basic fairness, and the ability of USP to claim public legitimacy as it makes pivotal judgments upon which industries, professions, and public health depend. We thank you for considering this one further submission and look forward to your prompt response. As always, we will be at your disposal if you wish to discuss.

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Source Document: Letter from Derek Shaffer to Mario Sindaco (Dec. 6, 2019).

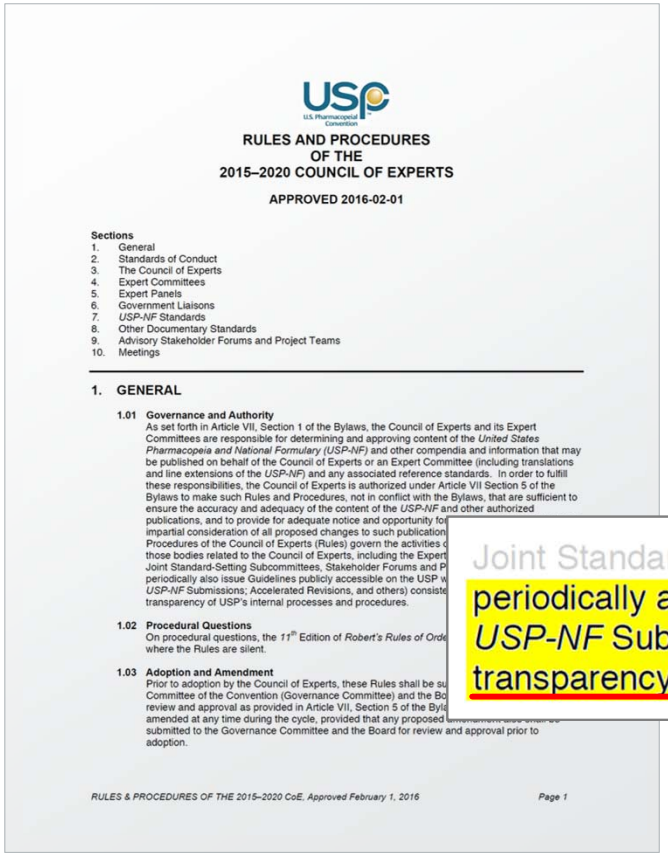
USP's Response

Conflicts of Interest: Why It Matters to the Coalition?

- Conflicts information is critical to assessing the legitimacy of the revisions to Chapters <795> and <797> and the extent to which these revisions were propelled by undisclosed influence(s).

- There is no way for the Panel to evaluate "***the sufficiency of the process used by the responsible Expert Committee to develop and approve the standards under appeal***" without knowing this information and the extent to which CEC members worked to push private and undisclosed interests. E-mail from M. Sindaco to S. Lerner (Oct. 30, 2019).

Conflicts of Interest: Why It Matters to USP?



RULES AND PROCEDURES
OF THE
2015–2020 COUNCIL OF EXPERTS

APPROVED 2016-02-01

Sections

1. General
2. Standards of Conduct
3. The Council of Experts
4. Expert Committees
5. Expert Panels
6. Government Liaisons
7. *USP-NF* Standards
8. Other Documentary Standards
9. Advisory Stakeholder Forums and Project Teams
10. Meetings

1. GENERAL

1.01 Governance and Authority
As set forth in Article VII, Section 1 of the Bylaws, the Council of Experts and its Expert Committees are responsible for determining and approving content of the *United States Pharmacopeia and National Formulary (USP-NF)* and other compendia and information that may be published on behalf of the Council of Experts or an Expert Committee (including translations and line extensions of the *USP-NF*) and any associated reference standards. In order to fulfill these responsibilities, the Council of Experts is authorized under Article VII Section 5 of the Bylaws to make such Rules and Procedures, not in conflict with the Bylaws, that are sufficient to ensure the accuracy and adequacy of the content of the *USP-NF* and other authorized publications, and to provide for adequate notice and opportunity for public comment and full and impartial consideration of all proposed changes to such publications. These Rules and Procedures of the Council of Experts (Rules) govern the activities of the Council of Experts and those bodies related to the Council of Experts, including the Expert Committees, Expert Panels, Joint Standard-Setting Subcommittees, Stakeholder Forums and Project Teams. USP staff may periodically also issue Guidelines publicly accessible on the USP website (e.g., Guidelines for *USP-NF* Submissions; Accelerated Revisions, and others) consistent with the Rules to promote transparency of USP's internal processes and procedures.

1.02 Procedural Questions
On procedural questions, the 11th Edition of *Robert's Rules of Orde*
where the Rules are silent.

1.03 Adoption and Amendment
Prior to adoption by the Council of Experts, these Rules shall be su
Committee of the Convention (Governance Committee) and the Bo
review and approval as provided in Article VII, Section 5 of the Byl
amended at any time during the cycle, provided that any proposed
submitted to the Governance Committee and the Board for review and approval prior to
adoption.

RULES & PROCEDURES OF THE 2015–2020 CoE, Approved February 1, 2016 Page 1

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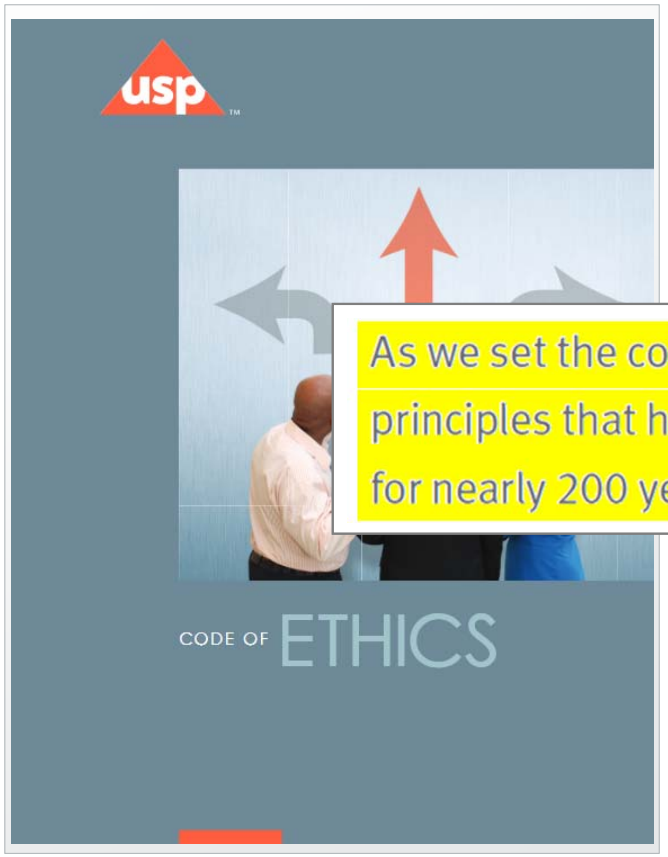
Joint Standard-Setting Subcommittees, Stakeholder Forums and Project Teams. USP staff may periodically also issue Guidelines publicly accessible on the USP website (e.g., Guidelines for *USP-NF* Submissions; Accelerated Revisions, and others) consistent with the Rules to promote transparency of USP's internal processes and procedures.

- USP's refusal to provide this information is contrary to USP's oft-stated ***commitment to transparency in standard-setting.***

Source Document: Rules and Procedures of the 2015-2020 USP Council of Experts (approved 02/01/2016), Sec. 1.01.

USP's Purported Commitment to "Collaboration and Transparency"




Dear Colleagues,

Thank you for your commitment to USP and to our mission of improving global health through public standards and related programs that help ensure the quality, safety, and benefits of medicines and food. Each of us plays an important day-to-day role in strengthening and growing our organization, and our individual and collective contributions are making an impact on the lives of millions of people around the world.

As we set the course for 2020 and beyond, it is important that we remain true to the principles that have made us a trusted and respected standards-setting organization for nearly 200 years. Our impact and achievements are deeply rooted in the rigorous

and I know that I can count on each of you to join us in this commitment.

Ronald T. Piervincenzi, Ph.D.
Chief Executive Officer

CODE OF ETHICS
LETTER FROM THE CEO


Ronald T. Piervincenzi, Ph.D.
Chief Executive Officer

Source Document: USP Code of Ethics (2015), p.iii.

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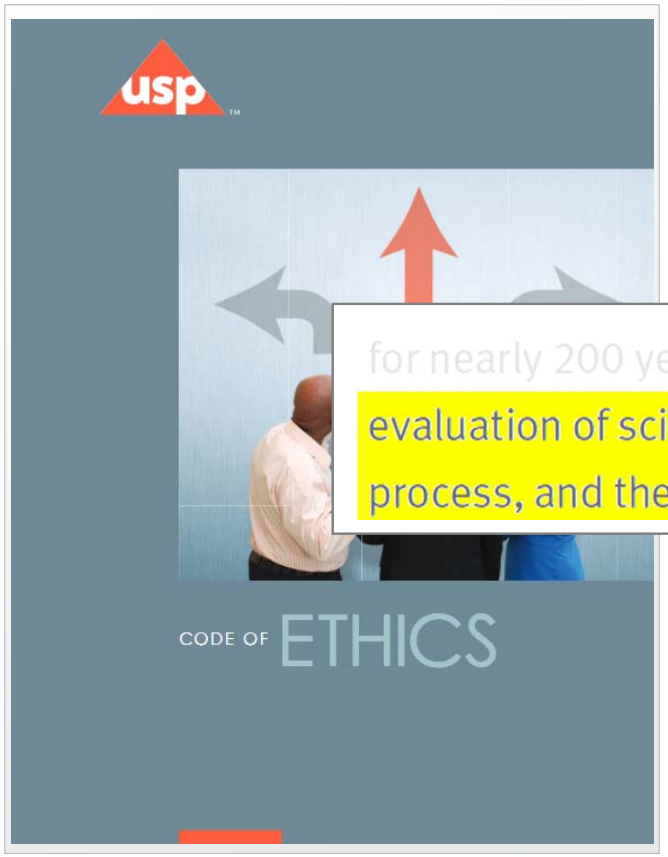

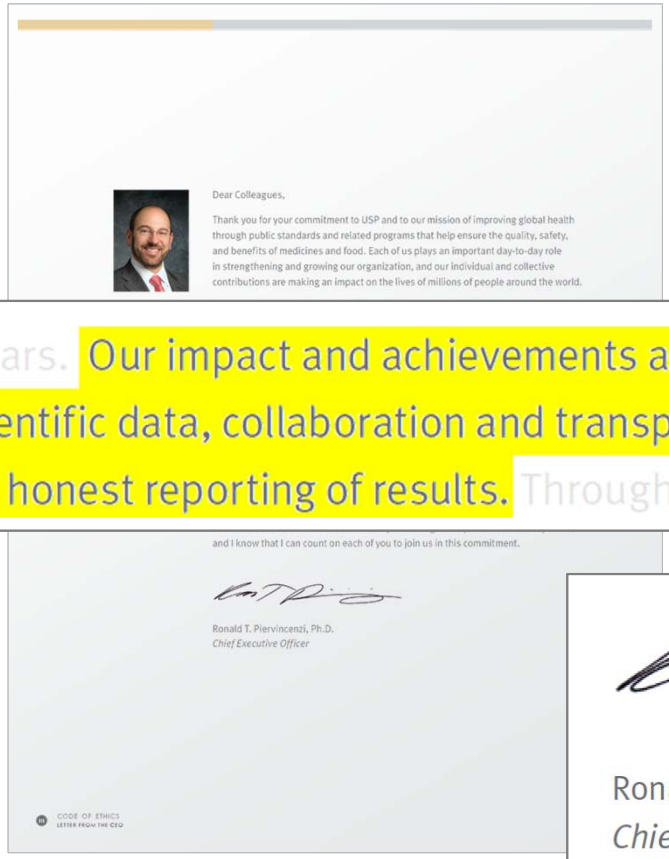

for nearly 200 years. Our impact and achievements are deeply rooted in the rigorous evaluation of scientific data, collaboration and transparency in the standards-setting process, and the honest reporting of results. Throughout our history, USP has been

Source Document: USP Code of Ethics (2015), p.iii.

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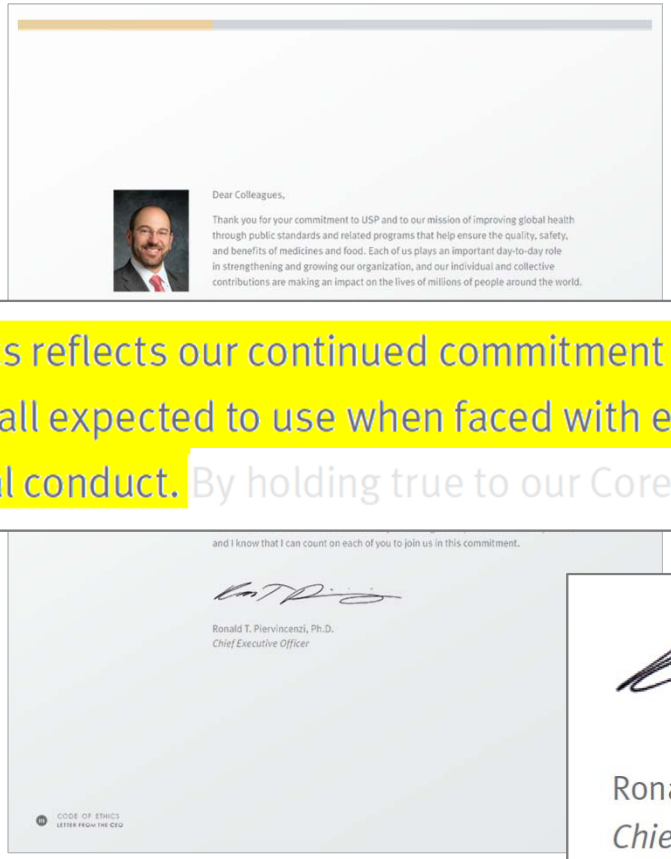


This Code of Ethics reflects our continued commitment to integrity and includes resources we are all expected to use when faced with ethical questions or if we observe illegal or unethical conduct. By holding true to our Core Values and operating with

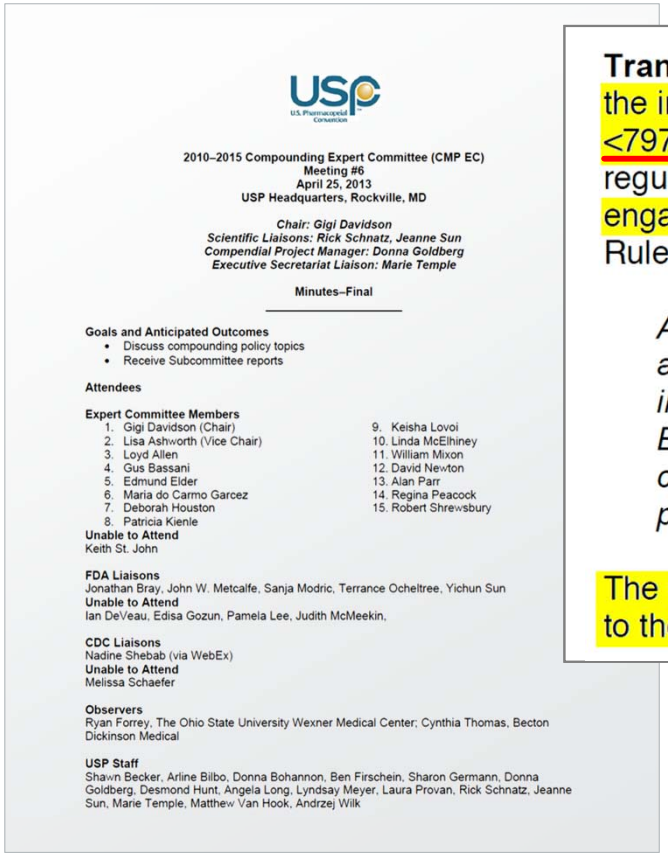
Source Document: USP Code of Ethics (2015), p.iii.

Conflict of Interest Case Study: Eric Kastango

Eric Kastango

- In October 2010, Eric Kastango was appointed by USP to chair the Chapter <797> Subcommittee.
- Mr. Kastango led the Chapter <797> Subcommittee's efforts to revise the Chapter **for nearly two and a half years, until April 2013**.

Conflict of Interest Case Study: Eric Kastango



2010–2015 Compounding Expert Committee (CMP EC)
Meeting #6
April 25, 2013
USP Headquarters, Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Rick Schnatz, Jeanne Sun
Compendial Project Manager: Donna Goldberg
Executive Secretariat Liaison: Marie Temple

Minutes–Final

Goals and Anticipated Outcomes
- Discuss compounding policy topics
- Receive Subcommittee reports

Attendees

Expert Committee Members
1. Gigi Davidson (Chair)
2. Lisa Ashworth (Vice Chair)
3. Loyd Allen
4. Gus Bassani
5. Edmund Elder
6. Maria do Carmo Garcez
7. Deborah Houston
8. Patricia Kienle
9. Keisha Lovoi
10. Linda McElhiney
11. William Mixon
12. David Newton
13. Alan Parr
14. Regina Peacock
15. Robert Shrewsbury

Unable to Attend
Keith St. John

FDA Liaisons
Jonathan Bray, John W. Metcalfe, Sanja Modric, Terrance Ocheltree, Yichun Sun
Unable to Attend
Ian DeVeau, Edisa Gozun, Pamela Lee, Judith McMeekin,

CDC Liaisons
Nadine Shebab (via WebEx)
Unable to Attend
Melissa Schaefer

Observers
Ryan Forrey, The Ohio State University Wexner Medical Center; Cynthia Thomas, Becton Dickinson Medical

USP Staff
Shawn Becker, Arline Bilbo, Donna Bohannon, Ben Firschein, Sharon Germann, Donna Goldberg, Desmond Hunt, Angela Long, Lyndsay Meyer, Laura Provan, Rick Schnatz, Jeanne Sun, Marie Temple, Matthew Van Hook, Andrzej Wilk

Transition: Mr. Eric Kastango announced that he has resigned from the CMP EC to protect the integrity of USP and its processes. His consulting work directly involves General Chapter <797>; he is involved with the application and enforcement of this General Chapter by state regulatory agencies. Although he will no longer be an EC member, USP will continue to engage him as an advisor on General Chapter <797> in accordance with Section 5.06 of the Rules and Procedures of the CoE, excerpted as follows:

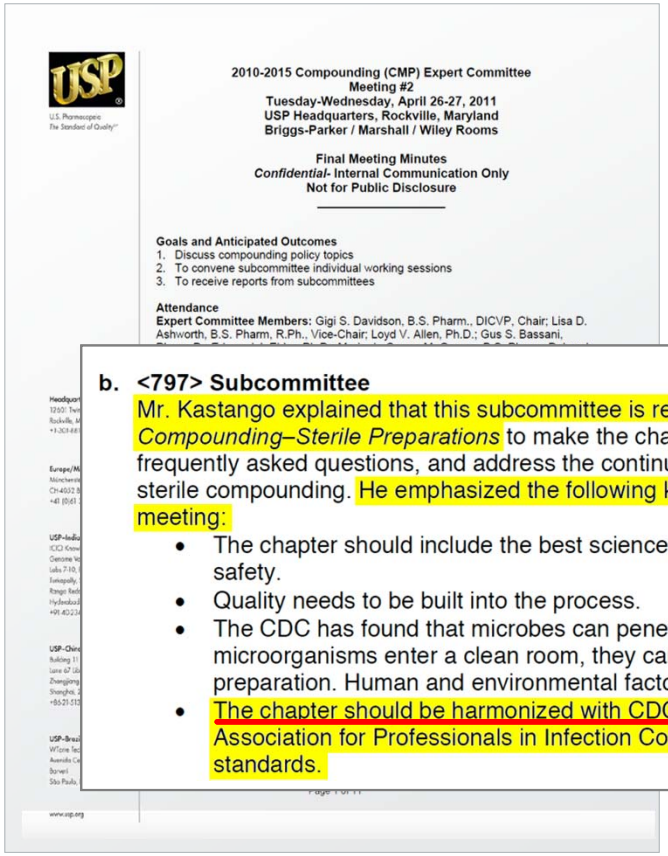
> *An Expert Committee may also request assistance from an individual who is not a CoE/EC Expert to participate in discussion or review documents where such individual provides necessary expertise not available within the Council of Experts or Expert Committees. Such individual shall be required to sign a confidentiality agreement requiring that the confidentiality of all information provided to such individual be maintained.*

The Chair, EC members, and USP staff recognized Mr. Kastango's extensive contributions to the CMP EC and General Chapter <797>.

- After working on the <797> Subcommittee for nearly two and a half years, Mr. Kastango resigned as its Chairman in April 2013 ***for undisclosed conflict-of-interest reasons***.

Source Document: Compounding Expert Committee Meeting Minutes (April 25, 2013), at p.3.

Conflict of Interest Case Study: Eric Kastango



2010-2015 Compounding (CMP) Expert Committee
Meeting #2
Tuesday-Wednesday, April 26-27, 2011
USP Headquarters, Rockville, Maryland
Briggs-Parker / Marshall / Wiley Rooms

Final Meeting Minutes
Confidential- Internal Communication Only
Not for Public Disclosure

Goals and Anticipated Outcomes
1. Discuss compounding policy topics
2. To convene subcommittee individual working sessions
3. To receive reports from subcommittees

Attendance
Expert Committee Members: Gigi S. Davidson, B.S. Pharm., DICVP, Chair; Lisa D. Ashworth, B.S. Pharm, R.Ph., Vice-Chair; Loyd V. Allen, Ph.D.; Gus S. Bassani,

b. <797> Subcommittee

Mr. Kastango explained that this subcommittee is revising <797> *Pharmaceutical Compounding–Sterile Preparations* to make the chapter more user friendly, incorporate frequently asked questions, and address the continuum of practitioners that practice sterile compounding. He emphasized the following key points discussed at the working meeting:

- The chapter should include the best science and procedures to ensure patient safety.
- Quality needs to be built into the process.
- The CDC has found that microbes can penetrate filters (e.g. *Serratia*). If microorganisms enter a clean room, they can contaminate a compounded preparation. Human and environmental factors must be controlled.
- The chapter should be harmonized with CDC and FDA guidances and Association for Professionals in Infection Control and Epidemiology (APIC) standards.

- The Chair announced that Mr. Kastango was conducting a <797> Compliance survey to establish the gaps in the Chapter and she asked him to inform the Committee of his efforts.
  - Mr. Kastango reported that he is working on a project that will survey pharmacy facilities on the compliance of GC <797>. This project will be led from his consulting group, Clinical IQ. He said the survey asks pharmacists if they comply with all of <797> or not. The intent is to capture feedback and all problems associated with the compliance of <797>; the survey is an anonymous web-based gap analysis tool.
  - Mr. Kastango said the survey will close in June or July and will be shared with the Committee and FDA. The goal is to publish the first-set of findings in the journal, Pharmacy, Purchasing & Products, by fall of this year. Dr. Allen said he would also be happy to consider publication of the results in his journal.

- Although the precise nature of Mr. Kastango's conflicts were never revealed, ***he had previously been a strong advocate for importing FDA guidelines into the Chapter <797> revisions*** and freely shared USP data with FDA.

Source Document: Compounding Expert Committee Meeting Minutes (April 26-27, 2011), at p.7; Compounding Expert Committee Meeting Minutes (Nov. 27-28, 2012), at p.7.

Conflict of Interest Case Study: Eric Kastango

USP
U.S. Pharmacopeial Convention

2010–2015 Compounding Expert Committee (CMP EC)
Meeting #6
April 25, 2013
USP Headquarters, Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Rick Schnatz, Jeanne Sun
Compendial Project Manager: Donna Goldberg
Executive Secretariat Liaison: Marie Temple

Minutes–Final

Goals and Anticipated Outcomes
- Discuss compounding policy topics
- Receive Subcommittee reports

Attendees

Expert Committee Members
1. Gigi Davidson (Chair)
2. Lisa Ashworth (Vice Chair)
3. Loyd Allen
4. Gus Bassani
5. Edmund Elder
6. Maria do Carmo Garcez
7. Deborah Houston
8. Patricia Kienle
9. Keisha Lovoi
10. Linda McElhiney
11. William Mixon
12. David Newton
13. Alan Parr
14. Regina Peacock
15. Robert Shrewsbury

Unable to Attend
Keith St. John

FDA Liaisons
Jonathan Bray, John W. Metcalfe, Sanja Modric, Terrance Ocheltree, Yichun Sun
Unable to Attend
Ian DeVeau, Edisa Gozun, Pamela Lee, Judith McMeekin,

CDC Liaisons
Nadine Shebab (via WebEx)
Unable to Attend
Melissa Schaefer

Observers
Ryan Forrey, The Ohio State University Wexner Medical Center; Cynthia Thomas, Becton Dickinson Medical

USP Staff
Shawn Becker, Arline Bilbo, Donna Bohannon, Ben Firschein, Sharon Germann, Donna Goldberg, Desmond Hunt, Angela Long, Lyndsay Meyer, Laura Provan, Rick Schnatz, Jeanne Sun, Marie Temple, Matthew Van Hook, Andrzej Wilk

Transition: Mr. Eric Kastango announced that he has resigned from the CMP EC to protect the integrity of USP and its processes. His consulting work directly involves General Chapter <797>; he is involved with the application and enforcement of this General Chapter by state regulatory agencies. Although he will no longer be an EC member, USP will continue to engage him as an advisor on General Chapter <797> in accordance with Section 5.06 of the Rules and Procedures of the CoE, excerpted as follows:

> *An Expert Committee may also request assistance from an individual who is not a CoE/EC Expert to participate in discussion or review documents where such individual provides necessary expertise not available within the Council of Experts or Expert Committees. Such individual shall be required to sign a confidentiality agreement requiring that the confidentiality of all information provided to such individual be maintained.*

The Chair, EC members, and USP staff recognized Mr. Kastango's extensive contributions to the CMP EC and General Chapter <797>.

- Despite acknowledging Mr. Kastango's "***extensive contributions***" to Chapter <797>, there is ***no indication*** USP ever reviewed Mr. Kastango's work through April 2013 to determine whether it was tainted or otherwise influenced by his acknowledged conflicts.

Source Document: Compounding Expert Committee Meeting Minutes (April 25, 2013), at p.3.

Conflict of Interest Case Study: Eric Kastango

USP
U.S. Pharmacopeial Convention

2010–2015 Compounding Expert Committee (CMP EC)
Meeting #6
April 25, 2013
USP Headquarters, Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Rick Schnatz, Jeanne Sun
Compendial Project Manager: Donna Goldberg
Executive Secretariat Liaison: Marie Temple

Minutes–Final

Goals and Anticipated Outcomes
- Discuss compounding policy topics
- Receive Subcommittee reports

Attendees

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2. Lisa Ashworth (Vice Chair)
3. Loyd Allen
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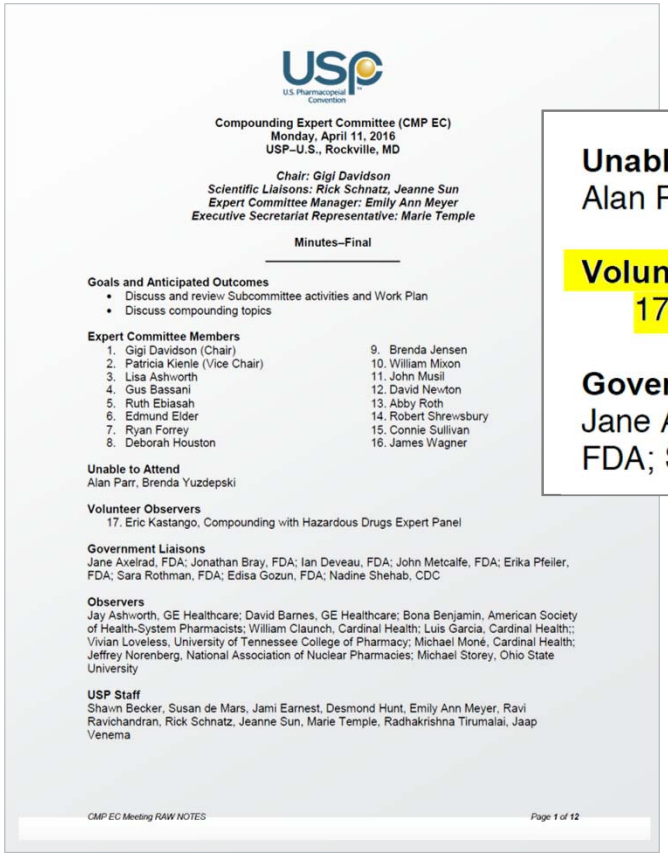
The Chair, EC members, and USP staff recognized Mr. Kastango's extensive contributions to the CMP EC and General Chapter <797>.

- Incredibly, ***USP continued to retain Mr. Kastango as an advisor*** on Chapter <797> despite his conflicts!!!

Source Document: Compounding Expert Committee Meeting Minutes (April 25, 2013), at p.3.

Conflict of Interest Case Study: Eric Kastango



USP
U.S. Pharmacopeial Convention

Compounding Expert Committee (CMP EC)
Monday, April 11, 2016
USP–U.S., Rockville, MD

Chair: Gigi Davidson
Scientific Liaisons: Rick Schnatz, Jeanne Sun
Expert Committee Manager: Emily Ann Meyer
Executive Secretariat Representative: Marie Temple

Minutes–Final

Goals and Anticipated Outcomes
- Discuss and review Subcommittee activities and Work Plan
- Discuss compounding topics

Expert Committee Members
1. Gigi Davidson (Chair)
2. Patricia Kienle (Vice Chair)
3. Lisa Ashworth
4. Gus Bassani
5. Ruth Ebiasah
6. Edmund Elder
7. Ryan Forrey
8. Deborah Houston
9. Brenda Jensen
10. William Mixon
11. John Musil
12. David Newton
13. Abby Roth
14. Robert Shrewsbury
15. Connie Sullivan
16. James Wagner

Unable to Attend
Alan Parr, Brenda Yuzdepski

Volunteer Observers
17. Eric Kastango, Compounding with Hazardous Drugs Expert Panel

Government Liaisons
Jane Axelrad, FDA; Jonathan Bray, FDA; Ian Deveau, FDA; John Metcalfe, FDA; Erika Pfeiler, FDA; Sara Rothman, FDA; Edisa Gozun, FDA; Nadine Shehab, CDC

Observers
Jay Ashworth, GE Healthcare; David Barnes, GE Healthcare; Bona Benjamin, American Society of Health-System Pharmacists; William Claunch, Cardinal Health; Luis Garcia, Cardinal Health;; Vivian Loveless, University of Tennessee College of Pharmacy; Michael Moné, Cardinal Health; Jeffrey Norenberg, National Association of Nuclear Pharmacies; Michael Storey, Ohio State University

USP Staff
Shawn Becker, Susan de Mars, Jami Earnest, Desmond Hunt, Emily Ann Meyer, Ravi Ravichandran, Rick Schnatz, Jeanne Sun, Marie Temple, Radhakrishna Tirumalai, Jaap Venema

CMP EC Meeting RAW NOTES *Page 1 of 12*

Unable to Attend
Alan Parr, Brenda Yuzdepski

Volunteer Observers
17. Eric Kastango, Compounding with Hazardous Drugs Expert Panel

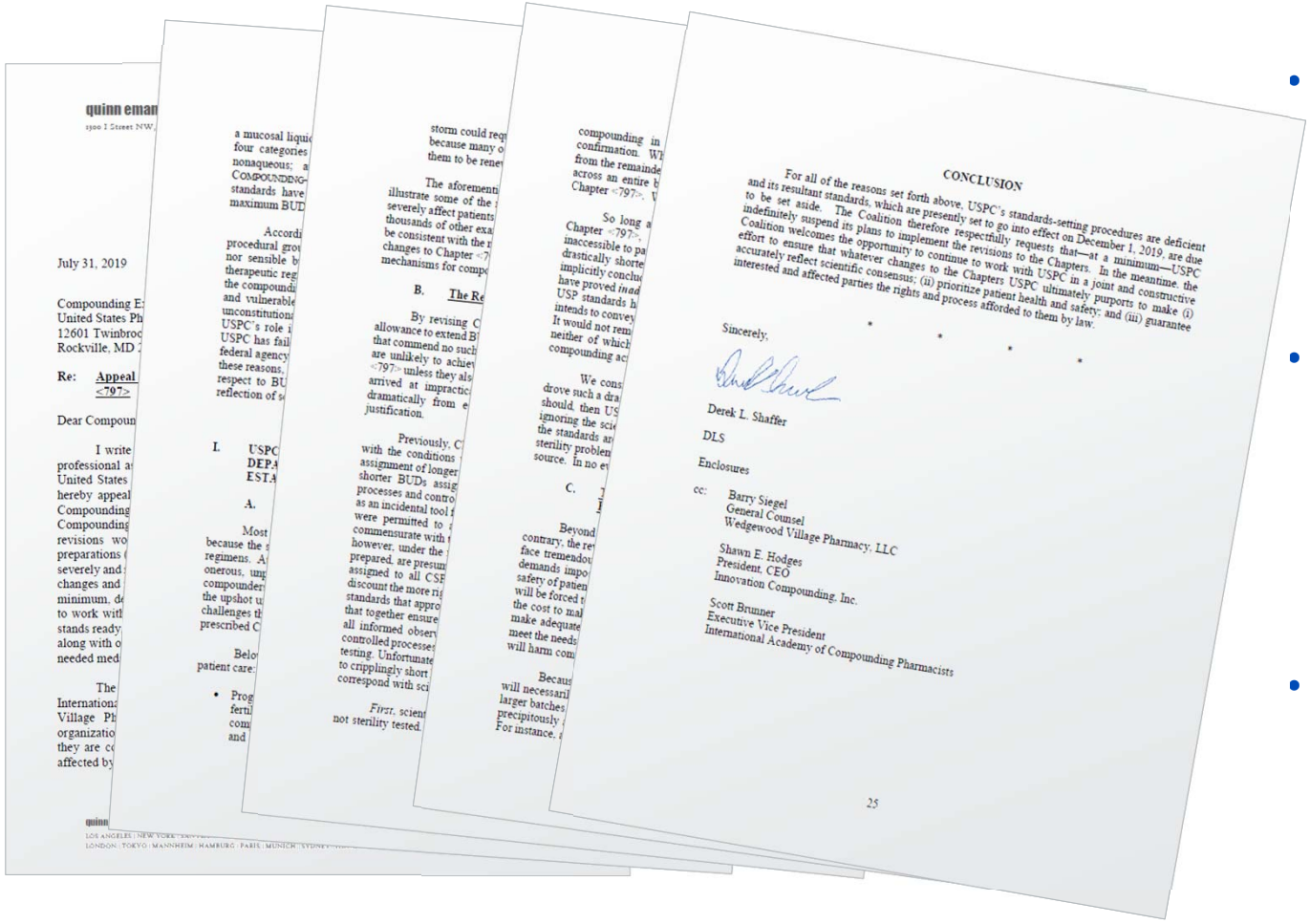
Government Liaisons
Jane Axelrad, FDA; Jonathan Bray, FDA; Ian Deveau, FDA; John Metcalfe, FDA; Erika Pfeiler, FDA; Sara Rothman, FDA; Edisa Gozun, FDA; Nadine Shehab, CDC

- Indeed, Mr. Kastango ***continued to attend CEC meetings*** until at least September 2016 in his capacity as an expert for another USP Expert Committee.

Source Document: Compounding Expert Committee Meeting Minutes (April 11, 2016), at p.1.

Problems with USP's Development of the Revised Chapters: *Key Input from FDA Withheld from the Public and the Coalition*

The Coalition Appeals the Revised Standards



CONCLUSION

For all of the reasons set forth above, USPC's standards-setting procedures are deficient and its resultant standards, which are presently set to go into effect on December 1, 2019, are due to be set aside. The Coalition therefore respectfully requests that—at a minimum—USPC indefinitely suspend its plans to implement the revisions to the Chapters. In the meantime, the Coalition welcomes the opportunity to continue to work with USPC in a joint and constructive effort to ensure that whatever changes to the Chapters USPC ultimately purports to make (i) accurately reflect scientific consensus; (ii) prioritize patient health and safety; and (iii) guarantee interested and affected parties the rights and process afforded to them by law.

* * * *

Sincerely,

Derek L. Shaffer

DLS

Enclosures

cc: Barry Siegel
General Counsel
Wedgewood Village Pharmacy, LLC

Shawn E. Hodges
President, CEO
Innovation Compounding, Inc.

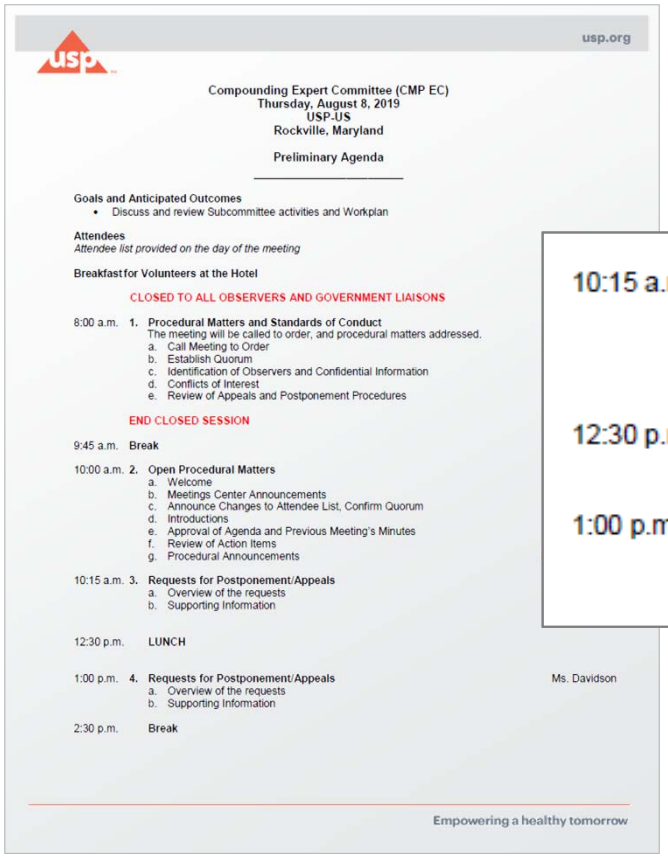
Scott Brunner
Executive Vice President
International Academy of Compounding Pharmacists

25

- The Coalition submitted its 25 single-spaced page appeal of the revised Chapters <795> and <797> to USP on July 31, 2019.
- The appeal set forth extensive factual and legal arguments as to how and why the revised standards are unsound scientifically, procedurally, and legally.
- Attached to the appeal were several exhibits supporting the Coalition's arguments.

Source Document: Appeal Letter from the Coalition to Compounding Expert Committee (July 31, 2019).

The Compounding Expert Committee Holds a Meeting on August 8, 2019



usp.org

Compounding Expert Committee (CMP EC)
Thursday, August 8, 2019
USP-US
Rockville, Maryland

Preliminary Agenda

Goals and Anticipated Outcomes
- Discuss and review Subcommittee activities and Workplan

Attendees
Attendee list provided on the day of the meeting

Breakfast for Volunteers at the Hotel

CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS

8:00 a.m. **1. Procedural Matters and Standards of Conduct**
The meeting will be called to order, and procedural matters addressed.
a. Call Meeting to Order
b. Establish Quorum
c. Identification of Observers and Confidential Information
d. Conflicts of Interest
e. Review of Appeals and Postponement Procedures

END CLOSED SESSION

9:45 a.m. **Break**

10:00 a.m. **2. Open Procedural Matters**
a. Welcome
b. Meetings Center Announcements
c. Announce Changes to Attendee List, Confirm Quorum
d. Introductions
e. Approval of Agenda and Previous Meeting's Minutes
f. Review of Action Items
g. Procedural Announcements

10:15 a.m. **3. Requests for Postponement/Appeals**
a. Overview of the requests
b. Supporting Information

12:30 p.m. **LUNCH**

1:00 p.m. **4. Requests for Postponement/Appeals** Ms. Davidson
a. Overview of the requests
b. Supporting Information

2:30 p.m. **Break**

Empowering a healthy tomorrow

10:15 a.m. **3. Requests for Postponement/Appeals** Ms. Davidson
a. Overview of the requests
b. Supporting Information

12:30 p.m. **LUNCH**

1:00 p.m. **4. Requests for Postponement/Appeals** Ms. Davidson
a. Overview of the requests
b. Supporting Information

Source Document: Compounding Expert Committee Meeting Minutes (Aug. 8, 2019), at p.1.

The Compounding Expert Committee Discloses, for the First Time, a Key FDA Input

U.S. FOOD & DRUG ADMINISTRATION

April 16, 2018

Ms. Shawn Becker
Senior Director, Healthcare Quality Standards
The United States Pharmacopeial Convention, Inc.
12601 Twinbrook Parkway
Rockville, MD 20852

Dear Ms. Becker:

FDA is writing to reiterate our concerns about the United States Pharmacopoeia (USP)'s proposal in the draft <797> for the assignment of beyond-use-dates (BUDs) to compounded sterile preparations (CSPs) based on the dating in the applicable USP monograph, if such a monograph exists. FDA is similarly concerned about the proposal to assign BUDs based on a stability study. Stability studies are not sufficient to model the risk of microbiological contamination of a product each time it is produced, nor are they sufficient to predict the growth characteristics of any contaminating microorganisms. Assigning long BUDs that are not sufficiently supported by comprehensive, scientific microbiological data, and that are not reviewed by a regulatory agency with experience with such studies, could lead to significant microbial growth in a compounded sterile preparation (CSP) that has been contaminated. This could significantly exacerbate the harm caused by administration of a contaminated compounded drug.

Assigning a BUD based on an applicable monograph

For the following reasons, FDA recommends that the compounding USP monographs reference table 8 in the draft <797> for assigning the BUD. The BUD for a CSP should not exceed that which is specified in Table 8, and the BUD may be shorter if there are stability concerns that, as reflected in the monograph, necessitate a shorter date. This approach would recognize that a CSP with a monograph that demonstrates physical and chemical stability at a longer date is not any less prone to sterility assurance concerns than a different substance that is not the subject of a monograph.

FDA recognizes that USP develops the dating in monographs based on robust stability studies that demonstrate the physical and chemical stability of the substance through the BUD. FDA also recognizes that the studies demonstrate that the container is appropriate such that it does not leach into or otherwise react with the drug product. However, stability studies do not sufficiently model the risk of microbiological contamination during production. For example, USP monographs do not specify manufacturing sterilization details, such as autoclave time and

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

- At the August 8, 2019 meeting, Ms. Gigi Davidson, the Chair of USP's CEC, disclosed for the ***first time***, that in April 2018 it received a letter from the FDA that was described as a ***critical input that USP relied upon in developing the revised <797> standards.***

Source Document: Letter from FDA to Shawn Becker, Senior Director, Healthcare Quality Standards, USP (April 16, 2018).

USP's Reliance on the April 2018 FDA Letter Was Misguided

- For one, the FDA's letter actually supports the arguments made in the Coalition's Appeal that sterility testing does not ensure sterility of CSPs.

U.S. FOOD & DRUG ADMINISTRATION

Sterility Testing

During a recent teleconference, USP suggested that performing a sterility test may mitigate FDA's concern with CSPs being labeled with BUDs that exceed the default BUDs in table 8. However, merely passing a sterility test does not indicate that a CSP batch is, in fact, sterile; rather, adequate sterility assurance is a result of all activities that take place in a facility, including robust environmental and personnel monitoring.[1] We note that the newest revision of the chapter has significantly decreased monitoring activities as compared to the initial draft chapter that appeared in the PF. Since not all these sterility assurance activities are accounted for in the monographs or in the newest revision of the chapter, BUDs unsupported by microbiological contamination risk data should be set conservatively, as reflected in table 8. The table 8 BUDs reflect a compromise that balance the quality risks associated with CSPs and the need for patient access to CSPs. Longer BUDs would require scientific support currently not required under the new revision to the chapter.

INNOVATION COMPOUNDING

Alliance for Pharmacy Compounding

wedgewood PHARMACY

First, scientific consensus does not suggest any need to shorten BUDs for CSPs that are not sterility tested. Whether or not sterility testing has been performed does not determine the compounder's ability to achieve or maintain sterility of a CSP. Indeed, relying upon "end-product sterility testing" over and above the "sterilization process" itself is "without scientific foundation and can lead to erroneous conclusions." T.A. du Plessis, *The Shelf Life of Sterile Medical Devices*, 13 S. AFR. ORTHOPAEDIC J. 32, 33–34 (2014) ("It clearly follows that end-product sterility testing of a few medical devices following sterilization to 'demonstrate' or 'prove' that the entire batch is sterile, without a proper prior process validation, ***is without scientific foundation and can lead to erroneous conclusions*** with regard to the sterility of the batch as a whole. . . . ***Provided a properly validated sterilization process is used***, and the integrity of the packaging is maintained, there is ***no reason to limit the shelf life of a sterile medical device***—especially so in the case of radiation sterilization" (emphasis added)) (attached hereto as Exhibit A); *see also* Frances W. Bowman, *The Sterility Testing of Pharmaceuticals*, 58 J. PHARMACEUTICAL SCI. 1301 (1969) (attached hereto as Exhibit B).

Source Document: Letter from FDA to Shawn Becker, USP (April 16, 2018); Appeal Letter from the Coalition to Compounding Expert Committee (July 31, 2019).

USP's Reliance on the April 2018 FDA Letter Was Misguided

U.S. FOOD & DRUG ADMINISTRATION

> Further, it is FDA's understanding that a concern that prompted USP to initiate the process of revising chapter <797> was that the standards in the current chapter can be interpreted in a variety of ways and have, therefore, presented difficulties both for compounders that seek to comply with them and states that seek to enforce them. For the standards that USP is developing to have a meaningful public health impact, it is critical that they be specific enough for compounders and regulatory authorities to understand what is expected. A provision for stability studies, without any guidance on what that entails, would likely be difficult to interpret and enforce uniformly.

> Further, as USP is aware, FDA does not conduct inspections of the vast majority of compounding pharmacies in the United States. States have primary day-to-day oversight over such pharmacies and may not have the expertise to review stability studies, which are not typically required by states' laws. As noted above, long BUDs based on flawed stability studies could have significant public health implications.

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- FDA's enlistment of <797> is misplaced.
- The problem is not that <797> is not up to the task.
- The problem is that a limited number of facilities were not complying with <797>, and the States do not, according to FDA, "have the expertise" needed to ensure compliance.
- The stated concerns do not hold for a facility like Wedgewood, which has not shown any contamination in any of the thousands of batches it has tested since 2014.

Source Document: Letter from FDA to Shawn Becker, USP (April 16, 2018).

USP's Reliance on the April 2018 FDA Letter Was Misguided

U.S. FOOD & DRUG ADMINISTRATION

INNOVATION COMPOUNDING

Alliance for Pharmacy Compounding

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Conclusion

As USP is aware, once a drug intended to be sterile is contaminated and the longer it is held before administration, the greater the potential for microbial proliferation. FDA has investigated numerous outbreaks associated with patients who received contaminated compounded drug products labeled with a long BUD.

FDA's concerns associated with the proposals to assign BUDs based on the dating in the monograph or a stability study are rooted in our experience responding to outbreaks associated with compounded drugs. Pharmacies, federal facilities, and physicians that compound sterile drug products look to USP standards to understand the practices and conditions that must be met to produce a sterile and otherwise high quality product. Many states similarly look to USP standards for inspections and enforcement. The revisions pertaining to BUDs would send a concerning signal to these entities that assigning a BUD based on monograph dating that is divorced from sterility assurance, or based on any stability study that they conduct no matter its content or rigor, is acceptable. This would constitute a significant loosening of the standards that USP initially proposed to raise the bar for sterile compounding broadly and decrease the potential for serious patient harm associated with contaminated compounded drug products.

- FDA's focus on "numerous outbreaks" involving patients who received contaminated CSPs "labeled with a long BUD" is unsupported.
- FDA does not identify (i) what outbreaks it is referring to; (ii) what facilities were at issue; (iii) whether these facilities were complying with <797>; or (iv) what products were at issue.
- USP needs specific information to evaluate FDA's reliance on these "numerous outbreaks."

Source Document: Letter from FDA to Shawn Becker, USP (April 16, 2018).

USP's Reliance on the April 2018 FDA Letter Was Misguided

U.S. FOOD & DRUG ADMINISTRATION

However, even if USP did provide detailed standards for conducting stability studies, concerns would remain. For example, FDA is concerned about the quality of the stability studies that compounders not subject to current good manufacturing practice requirements may conduct. To conduct a meaningful study that demonstrates that a drug product is sterile and stable through its BUD, an entity must conduct a number of tests that, in FDA's experience, state-licensed pharmacies, federal facilities, and physicians do not typically perform and are beyond their capabilities. When FDA has reviewed or become aware of stability studies conducted by compounding pharmacies, they have been deficient. For example, during a recent inspection, FDA noted that although a compounding pharmacy assigned a BUD to a drug product based on a stability study, FDA laboratory analysis of the drug product, which was within its BUD, revealed that it was 1% of its labeled potency.

INNOVATION COMPOUNDING

Alliance for Pharmacy Compounding

wedgewood PHARMACY

July 31, 2019

Compounding Expert Committee
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: **Appeal of Revisions of Beyond-Use Date Standards in General Chapters <795> and <797>**

Dear Compounding Expert Committee:

I write respectfully to appeal on behalf of a coalition of compounding pharmacies and professional associations ("Coalition") pursuant to Article VII, Section 7 of the Bylaws of the United States Pharmacopeia Convention ("USPC"). Specifically, the undersigned Coalition is

* * *

to work with stakeholders to ensure patient access and safety. At the same time, the Coalition stands ready, willing, and able to assist the Expert Committee in arriving at appropriate BUD dates along with other protocols that both protect the interests of the public and ensure patient access to needed medications.

Source Document: Letter from FDA to Shawn Becker, USP (April 16, 2018); Appeal Letter from the Coalition to Compounding Expert Committee (July 31, 2019).

Problem with USP's Reliance on the April 2018 FDA Letter

- All interested and relevant parties must be involved in the standard-setting process.
- USP cannot rely upon FDA's private, unilateral submissions (sent outside official notice and comment channels) without informing the public of those submissions or making them available to the public for comment.
- The withholding of the FDA letter renders the notice and comment period deficient and unreliable as it prevents USP from obtaining a balanced set of inputs.

Problems with USP's Development of the Revised Chapters: *USP Overlooked Scientific Evidence and Practical Realities*

USP's Revisions Depart from and Ignore Scientific Consensus

Printed on: Mon Jul 29 2019, 19:46:54 pm
Printed by: Mark Boesen
Not Yet Official as of: 29-Jul-2019
To be Official on: 1-Dec-2019
DocId:GUID-A4CAAA88-6F02-4AB8-8628-09E102CB0703_4_en-US
Printed from:https://online.uspnf.com/uspnf/document/GUID-A4CAAA88-6F02-4AB8-8628-09E102CB0703_4_en-US
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⟨797⟩ PHARMACEUTICAL COMPOUNDING—STERILE PREPARATIONS

Change to read:

*TABLE OF CONTENTS

- By revising Chapter <797> so as to incorporate substantially shortened BUDs with no allowance to extend BUDs, ***USP ignored overwhelming scientific evidence and consensus to the contrary.***

Source Document: USP General Chapter <797> (June 2019).

USP's Revisions Depart from and Ignore Scientific Consensus

Printed on: Mon Jul 29 2019, 19:46:54 pm
Printed by: Mark Boesen
Not Yet Official as of: 29-Jul-2019
To be Official on: 1-Dec-2019
DocId:GUID-A4CAAA88-6F02-4AB8-8628-09E102CB0703_4_en-US
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⟨797⟩ PHARMACEUTICAL COMPOUNDING—STERILE PREPARATIONS

Change to read:

*TABLE OF CONTENTS

12.2 Sterility Testing

Sterility testing is not required for Category 1 CSPs (see *Table 10*). If a Category 2 CSP is assigned a BUD that requires sterility testing (see *Table 11*), the testing must be performed according to ⟨71⟩ or a validated alternative method (see *Validation of Alternative Microbiological Methods* ⟨1223⟩) that is non-inferior to ⟨71⟩ testing.

If sterility testing is performed, the minimum quantity of each container to be tested for each media is specified in *Sterility Tests* ⟨71⟩, *Table 2*, and the number of containers required to be tested in relation to the batch size is specified in *Sterility Tests* ⟨71⟩, *Table 3*, except as described below.

If the number of CSPs to be compounded in a single batch is less than the number of CSPs needed for testing as specified in *Sterility Tests* ⟨71⟩, *Table 3*, additional units must be compounded to be able to perform sterility testing as follows:

- If between 1 and 39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number. For example:
  - If 1 CSP is compounded, 10% of 1 rounded up to the next whole number would indicate that 1 additional CSP must be prepared for sterility testing.
  - If 39 CSPs are compounded, 10% of 39 rounded up to the next whole number would indicate that 4 additional CSPs must be prepared for sterility testing.

If more than 40 CSPs are prepared in a single batch, the sample sizes specified in *Sterility Tests* ⟨71⟩, *Table 3* must be used.

If sterility testing is performed according to ⟨71⟩, a *Sterility Tests* ⟨71⟩, *Method Suitability Test* must be performed to ensure that contamination can be recovered. If performing sterility testing according to ⟨71⟩, the *Sterility Tests* ⟨71⟩, *Test for Sterility of the Product to Be Examined, Membrane Filtration* method is the method of choice when the CSP formulation permits. The preferred alternative is the ⟨71⟩, *Test for Sterility of the Product to Be Examined, Direct Inoculation of the Culture Medium* method. If an alternative method is used for sterility testing, the method must be validated (see ⟨1223⟩) and demonstrated to be suitable for that CSP formulation.

Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented.

- USP decided inexplicably that compounders ***are unlikely to achieve or maintain sterility when preparing CSPs in accordance with Chapter <797> unless they also perform unnecessary and expensive sterility testing.***

Source Document: USP General Chapter <797> (June 2019), Sec. 12.2.

USP's Revisions Depart from and Ignore Scientific Consensus

The shelf life of sterile medical devices

TA du Plessis, MSc(Physics), DSc(Chem)
Gammatron (Pty) Ltd, Modimolle, Limpopo

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Email: gammatron@mweb.co.za

Abstract

The issues of the shelf life of sterile medical devices and the concept of end-product sterility testing of a sample of devices to prove the sterility of a batch of sterile devices are discussed against the background of the probabilistic approach to sterility and sterilisation. The particular role that the sterilisation technique and the packaging materials used play in maintaining sterility are discussed against the background that sterility and the maintenance thereof is event- and not time-related, and the implications thereof on the shelf life of sterile medical devices.

Key words: sterile medical devices, sterility maintenance, shelf life

Introduction

What limits the duration of the sterility of sterile medical devices?

Manufacturers of sterile medical devices often give an expiry ('use by') date on the package, generally five years from the date of sterilisation. The question arises as to what limits the duration of the sterility of such devices? Why is the shelf life limited by manufacturers, and if so, why specifically five years and not three or ten years – probably relating to the accelerated or real-time testing of the packaging material? This becomes particularly relevant in the case of medical implants such as prostheses. If the implant is specified by the manufacturer to have a shelf life of five years prior to implantation, how does this relate to the *in vivo* performance of the device? It should be clearly pointed out that in this discussion the emphasis is put on the sterility of the implant and not on the mechano-clinical performance of such a device.

In order to get perspective on this issue, it is necessary that we clearly understand the underlying principles of the particular sterilisation technique and the associated packaging of sterile medical devices.

The concepts of sterile, sterilisation and sterility assurance levels

In many authoritative books in the field of sterilisation, the concept sterile is referred to as a state completely free of any viable microorganisms, and sterilisation is defined as the process which will destroy all viable microorganisms.[1,2]

These concepts are thus used in the *absolute* sense where no viable microorganisms exist.

However, an inherent problem is that it is *impossible in practice to prove either the complete absence or the destruction of these microorganisms*.[3] This will be discussed in more detail later.

The fact that the destruction of microorganisms through physical (radiation and steam) and chemical (ethylene oxide) sterilisation methods shows an *exponential dependence* on the various process parameters, clearly implies that the absence of microorganisms on a medical device following a properly validated sterilisation process can only be described in terms of a *probability function*.[4] This exponential nature of sterilisation means that, although the probability may reach a very low value, *it can never be lowered to a zero level in the absolute sense of the word*.[4]

This probabilistic approach to sterility leads to the concept of sterility levels – a view which no doubt may have little room in the 'classical' approach to sterility. Such a probabilistic approach also implies the existence of certain 'sterility assurance levels' (SALs) – a concept that plays an important role in this field and is being used to quantify the level or probability of sterility achieved through a certain sterilisation process.[4]

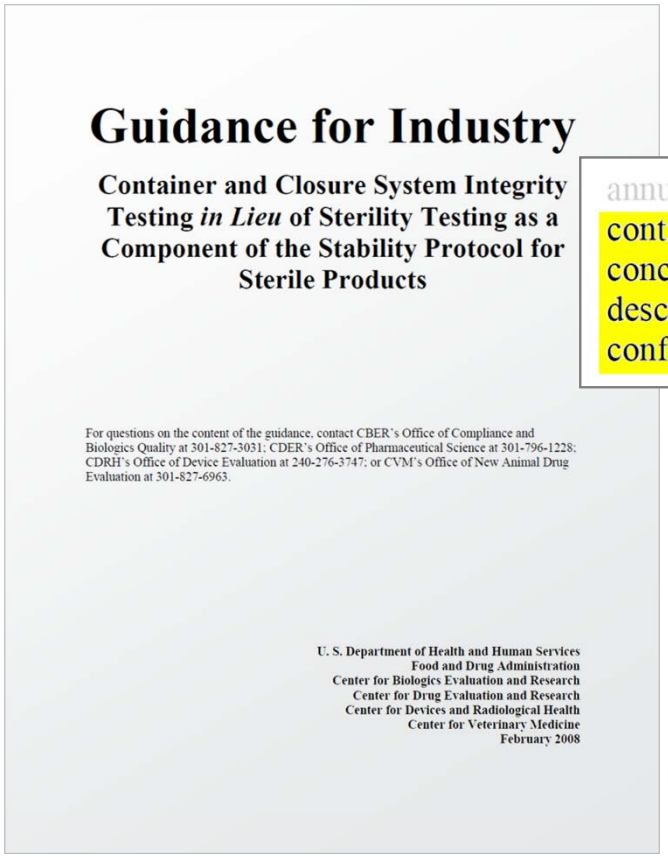
It clearly follows that end-product sterility testing of a few medical devices following sterilisation to 'demonstrate' or 'prove' that the entire batch is sterile, without a proper prior process validation, is without scientific foundation and can lead to erroneous conclusions with regard to the sterility of the batch as a whole.

Provided a properly validated sterilisation process is used, and the integrity of the packaging is maintained, there is no reason to limit the shelf life of a sterile medical device – especially so in the case of radiation sterilisation.

- Whether or not sterility testing has been performed ***does not determine the compounder's ability to achieve or maintain sterility of a CSP.***

Source Document: T.A. du Plessis, *The Shelf Life of Sterile Medical Devices*, 13 S. AFR. ORTHOPAEDIC J. 32, 33–34 (2014).

USP's Revisions Depart from and Ignore Scientific Consensus



Guidance for Industry

Container and Closure System Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products

For questions on the content of the guidance, contact CBER's Office of Compliance and Biologics Quality at 301-827-3031; CDER's Office of Pharmaceutical Science at 301-796-1228; CDRH's Office of Device Evaluation at 240-276-3747; or CVM's Office of New Animal Drug Evaluation at 301-827-6963.

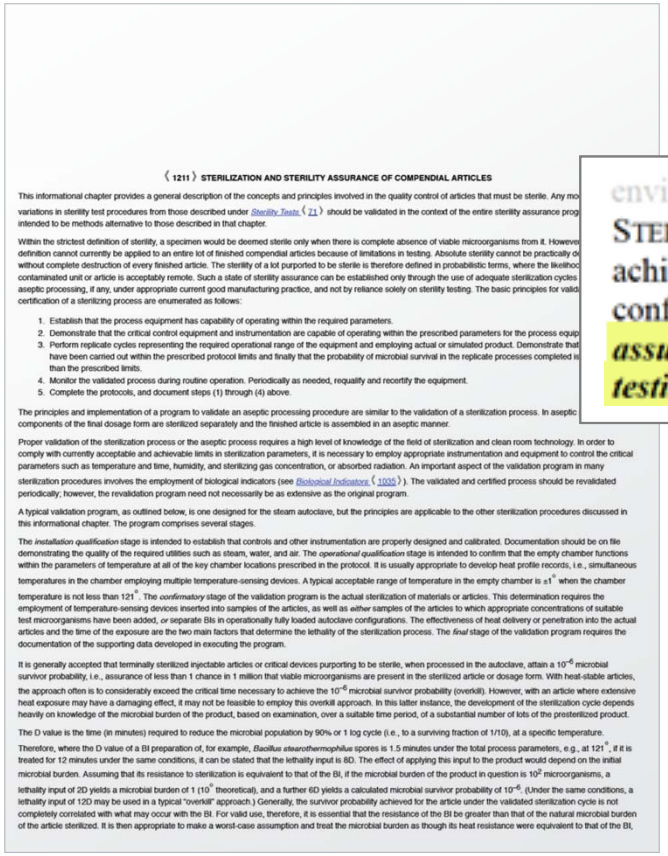
U. S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Center for Devices and Radiological Health
Center for Veterinary Medicine
February 2008

annually). However, as discussed below sterility tests for the purpose of demonstrating continuing sterility have limitations, with respect to the method's reliability, accuracy, and the conclusions that may be derived from the results. Because of the limitations of sterility tests described below, sterility tests are not recommended as a component of a stability program for confirming the continued sterility throughout a product's shelf life or dating period. Alternative

- Even FDA guidance casts doubt on the need for sterility testing to ensure sterility: "***sterility tests are not recommended as a component of a stability program for confirming the continued sterility*** throughout a product's shelf life or dating period."

Source Document: Food and Drug Admin., Guidance for Industry: Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products (2008), at p.2.

USP's Revisions Depart from and Ignore Scientific Consensus



〈1211〉 STERILIZATION AND STERILITY ASSURANCE OF COMPENDIAL ARTICLES

This informational chapter provides a general description of the concepts and principles involved in the quality control of articles that must be sterile. Any mo
variations in sterility test procedures from those described under *Sterility Tests* 〈71〉 should be validated in the context of the entire sterility assurance prog
intended to be methods alternative to those described in that chapter.

Within the strictest definition of sterility, a specimen would be deemed sterile only when there is complete absence of viable microorganisms from it. Howeve
definition cannot currently be applied to an entire lot of finished compendial articles because of limitations in testing. Absolute sterility cannot be practically d
without complete destruction of every finished article. The sterility of a lot purported to be sterile is therefore defined in probabilistic terms, where the likelihoc
contaminated unit or article is acceptably remote. Such a state of sterility assurance can be established only through the use of adequate sterilization cycles
aseptic processing, if any, under appropriate current good manufacturing practice, and not by reliance solely on sterility testing. The basic principles for valid
certification of a sterilizing process are enumerated as follows:

1. Establish that the process equipment has capability of operating within the required parameters.
2. Demonstrate that the critical control equipment and instrumentation are capable of operating within the prescribed parameters for the process equip
3. Perform replicate cycles representing the required operational range of the equipment and employing actual or simulated product. Demonstrate that
have been carried out within the prescribed protocol limits and finally that the probability of microbial survival in the replicate processes completed is
than the prescribed limits.
4. Monitor the validated process during routine operation. Periodically as needed, requalify and recertify the equipment.
5. Complete the protocols, and document steps (1) through (4) above.

The principles and implementation of a program to validate an aseptic processing procedure are similar to the validation of a sterilization process. In aseptic
components of the final dosage form are sterilized separately and the finished article is assembled in an aseptic manner.

Proper validation of the sterilization process or the aseptic process requires a high level of knowledge of the field of sterilization and clean room technology. In order to
comply with currently acceptable and achievable limits in sterilization parameters, it is necessary to employ appropriate instrumentation and equipment to control the critical
parameters such as temperature and time, humidity, and sterilizing gas concentration, or absorbed radiation. An important aspect of the validation program in many
sterilization procedures involves the employment of biological indicators (see *Biological Indicators* 〈1035〉). The validated and certified process should be revalidated
periodically; however, the revalidation program need not necessarily be as extensive as the original program.

A typical validation program, as outlined below, is one designed for the steam autoclave, but the principles are applicable to the other sterilization procedures discussed in
this informational chapter. The program comprises several stages.

The *installation qualification* stage is intended to establish that controls and other instrumentation are properly designed and calibrated. Documentation should be on file
demonstrating the quality of the required utilities such as steam, water, and air. The *operational qualification* stage is intended to confirm that the empty chamber functions
within the parameters of temperature at all of the key chamber locations prescribed in the protocol. It is usually appropriate to develop heat profile records, i.e., simultaneous
temperatures in the chamber employing multiple temperature-sensing devices. A typical acceptable range of temperature in the empty chamber is ±1° when the chamber
temperature is not less than 121°. The *confirmatory* stage of the validation program is the actual sterilization of materials or articles. This determination requires the
employment of temperature-sensing devices inserted into samples of the articles, as well as *either* samples of the articles to which appropriate concentrations of suitable
test microorganisms have been added, *or* separate BIs in operationally fully loaded autoclave configurations. The effectiveness of heat delivery or penetration into the actual
articles and the time of the exposure are the two main factors that determine the lethality of the sterilization process. The *final* stage of the validation program requires the
documentation of the supporting data developed in executing the program.

It is generally accepted that terminally sterilized injectable articles or critical devices purporting to be sterile, when processed in the autoclave, attain a 10^{-6} microbial
survivor probability, i.e., assurance of less than 1 chance in 1 million that viable microorganisms are present in the sterilized article or dosage form. With heat-stable articles,
the approach often is to considerably exceed the critical time necessary to achieve the 10^{-6} microbial survivor probability (overkill). However, with an article where extensive
heat exposure may have a damaging effect, it may not be feasible to employ this overkill approach. In this latter instance, the development of the sterilization cycle depends
heavily on knowledge of the microbial burden of the product, based on examination, over a suitable time period, of a substantial number of lots of the presterilized product.

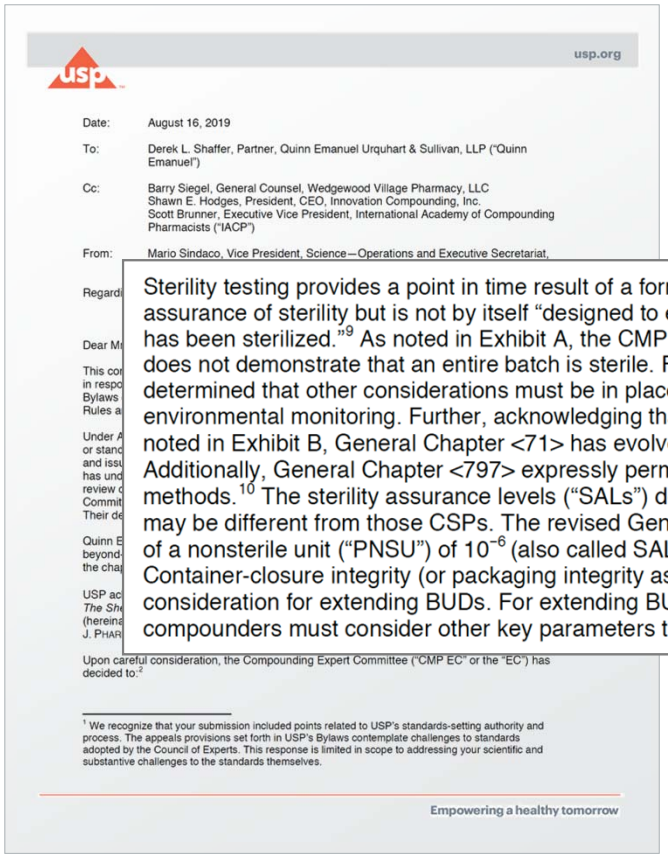
The D value is the time (in minutes) required to reduce the microbial population by 90% or 1 log cycle (i.e., to a surviving fraction of 1/10), at a specific temperature.
Therefore, where the D value of a BI preparation of, for example, *Bacillus stearothermophilus* spores is 1.5 minutes under the total process parameters, e.g., at 121°, if it is
treated for 12 minutes under the same conditions, it can be stated that the lethality input is 8D. The effect of applying this input to the product would depend on the initial
microbial burden. Assuming that its resistance to sterilization is equivalent to that of the BI, if the microbial burden of the product in question is 10^2 microorganisms, a
lethality input of 2D yields a microbial burden of 1 (10^2 theoretical), and a further 6D yields a calculated microbial survivor probability of 10^{-6}. (Under the same conditions, a
lethality input of 12D may be used in a typical "overkill" approach.) Generally, the survivor probability achieved for the article under the validated sterilization cycle is not
completely correlated with what may occur with the BI. For valid use, therefore, it is essential that the resistance of the BI be greater than that of the natural microbial burden
of the article sterilized. It is then appropriate to make a worst-case assumption and treat the microbial burden as though its heat resistance were equivalent to that of the BI,

environment, as other provisions of the USP recognize. *See* USP GENERAL CHAPTER <1211> STERILITY ASSURANCE ("CHAPTER <1211>") 8008 ("In a real sense, microbiological safety is achieved through the implementation of interrelated controls that in combination provide confidence that the items are suitable for use as labeled. ***It is the controls that provide the desired assurance from microbiological risk rather than the results of any in-process or finished goods testing.***" (emphasis added)). In sum, scientific consensus calls into serious question whether the

- Instead, what matters most is ***whether a compounder strictly adheres to best practices for establishing and maintaining a sterile environment***, as other provisions of the USP standards recognize.

Source Document: USP General Chapter <1211> Sterility Assurance ("Chapter<1211>") 8008.

USP's Revisions Depart from and Ignore Scientific Consensus



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Date: August 16, 2019

To: Derek L. Shaffer, Partner, Quinn Emanuel Urquhart & Sullivan, LLP ("Quinn Emanuel")

Cc: Barry Siegel, General Counsel, Wedgewood Village Pharmacy, LLC
Shawn E. Hodges, President, CEO, Innovation Compounding, Inc.
Scott Brunner, Executive Vice President, International Academy of Compounding Pharmacists ("IACP")

From: Mario Sindaco, Vice President, Science—Operations and Executive Secretariat,

Regard

Dear M

This co
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Bylaws
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J. PHAR

Upon careful consideration, the Compounding Expert Committee ("CMP EC" or the "EC") has decided to:[2]

[1] We recognize that your submission included points related to USP's standards-setting authority and process. The appeals provisions set forth in USP's Bylaws contemplate challenges to standards adopted by the Council of Experts. This response is limited in scope to addressing your scientific and substantive challenges to the standards themselves.

Empowering a healthy tomorrow

Sterility testing provides a point in time result of a formulation and provides some level of assurance of sterility but is not by itself "designed to ensure that a batch of product is sterile or has been sterilized."[9] As noted in Exhibit A, the CMP EC agrees that sterility testing alone does not demonstrate that an entire batch is sterile. For extending BUDs, the CMP EC determined that other considerations must be in place such as more frequent personnel and environmental monitoring. Further, acknowledging that sterility testing is changing rapidly, as noted in Exhibit B, General Chapter <71> has evolved and has been revised since 1969. Additionally, General Chapter <797> expressly permits validated alternative sterility testing methods.[10] The sterility assurance levels ("SALs") described in Exhibit A for medical devices may be different from those CSPs. The revised General Chapter <797> describes probability of a nonsterile unit ("PNSU") of 10^{-6} (also called SAL) for terminal sterilization methods. Container-closure integrity (or packaging integrity as noted in Exhibit A) is also an important consideration for extending BUDs. For extending BUDs beyond those in *Table 11*, compounders must consider other key parameters to ensure both stability and sterility.

- USP ***casually dismisses*** the Coalition's arguments as to:
  - the ***lack of scientific consensus for shortening the BUD*** for CSPs that have not undergone sterility testing;
  - the ***illogical differences*** between the maximum BUDs for room temperature, refrigerated, and frozen BUDs;
  - the ***internal inconsistency*** between the revised BUD standards in Chapters <795> and <797> and sterility assurance protocols in other USP General Chapters;
  - why sterility testing is preferable to policing the actual sterilization processes and methods used to prepare the CSPs.

Source Document: Letter from Mario Sindaco to Derek Shaffer (Aug. 16, 2019).

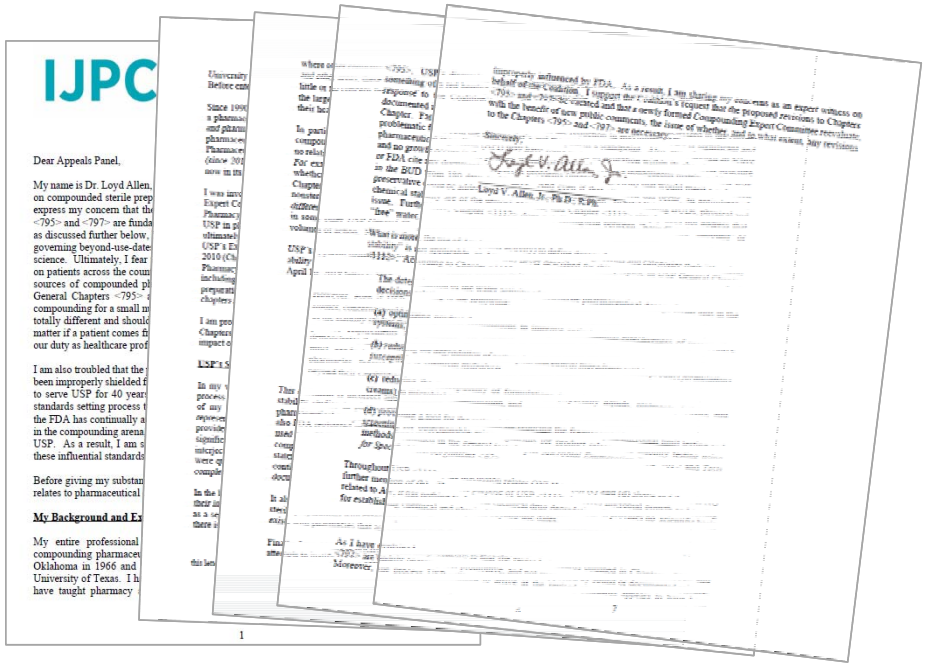
USP's Revisions Depart from and Ignore Scientific Consensus

Dr. Loyd Allen

- Practiced compounding pharmaceuticals in the community and hospital settings.
- As a professor, taught courses in compounding pharmacy as well as formulations, physical chemistry, pharmaceutical analysis, and dispensing.
- Published extensively on compounding topics, including authoring *The Art, Science, and Technology of Pharmaceutical Compounding* (5 editions) and *Allen's Compounded Formulations: A Complete U.S. Pharmacist Collection*.
- Editor-in-Chief, International Journal of Pharmaceutical Compounding (1996-Present).
- Extensive experience on USP's compounding pharmaceutical committees. *See, e.g.*, Pharmacy Compounding Practice Advisory Panel (1990-2000); USP Expert Committee on Nonsterile Compounding (2000-2013).

USP's Revisions Depart from and Ignore Scientific Consensus

Dr. Loyd Allen



IJPC

Dear Appeals Panel,

My name is Dr. Loyd Allen,
on compounded sterile prep
express my concern that th
<795> and <797> are funda
as discussed further below,
governing beyond-use-date
science. Ultimately, I fear
on patients across the coun
sources of compounded pl
General Chapters <795>
compounding for a small n
totally different and should
matter if a patient comes fi
our duty as healthcare prof

I am also troubled that the
been improperly shielded f
to serve USP for 40 year
standards setting process t
the FDA has continually a
in the compounding arena
USP. As a result, I am s
these influential standards

Before giving my substan
relates to pharmaceutical

My Background and Ex

My entire professional
compounding pharmacet
Oklahoma in 1966 and
University of Texas. I h
have taught pharmacy

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- "***My view of the revised Chapters <795> and <797> is that they are generally not scientifically supported by any evidence***, but rather by 'opinions' and what some individuals think 'should be done.' It seems that in many cases the new requirements for compounding activities are similar or the same as the requirements for manufacturing facilities. Thus, there is only a threshold level of compliance and not a graduated hierarchy to allow lower-risk facilities some leeway to serve their patients safely and effectively. The risk factors are different, but are not addressed in the standards. There is, evidently, no scientific data showing that the previous Chapters <795> and <797> were problematic and required revisions—only opinions." Letter from L. Allen to USP Appeals Panel (Jan. 21, 2020), at 4.

- "***[T]he issue of greatest concern regarding the revised compounding chapters is their failure to account for the differences in small- versus large-scale compounding***. In the past, these chapters have been fairly reasonable and achievable with the goal of enhancing the quality of compounded preparations. . . However, the standards recently published by USP are far more onerous, cost-prohibitive, and appear to be patterned after industry standards where tens of thousands of dosage units are made." *Id.*

- "In particular, a serious problem is that there are no graduated levels for nonsterile or sterile compounding based upon the number of preparations compounded daily. ***In other words, there is no relationship between the USP standards and the level of compounding activity a pharmacy does***. For example, if a compounding pharmacy does one (1) compounded prescription per day— whether sterile or nonsterile or hazardous, etc.—it is required to be completely compliant with the Chapters the same as if they do five hundred compounded prescriptions a day, whether sterile or nonsterile or hazardous, etc. This does not seem rational, as the risk levels are considerably different for the pharmacies and personnel involved." *Id.* at 5.

Source Document: Letter from L. Allen to USP Appeals Panel (Jan. 21, 2020).

USP's Revisions Overlook Practical Realities

- USP's revisions to Chapters <795> and <797> will have a number of harmful consequences that will severely impact patients and compounders alike, including:

  1. Making essential compounds more ***difficult to obtain or altogether unavailable,*** thereby disrupting the continuity of care for various patient groups, including pregnant women, patients undergoing fertility treatments, cancer patients, elderly patients, and pets, and the list goes on…;

  2. ***Raising unit costs*** to a degree that imposes extreme financial hardship on patients, particularly those who are socio-economically disadvantaged;

  3. Forcing compounders to make ***smaller batches*** that introduce ***greater risk of error and reduce overall safety***; and

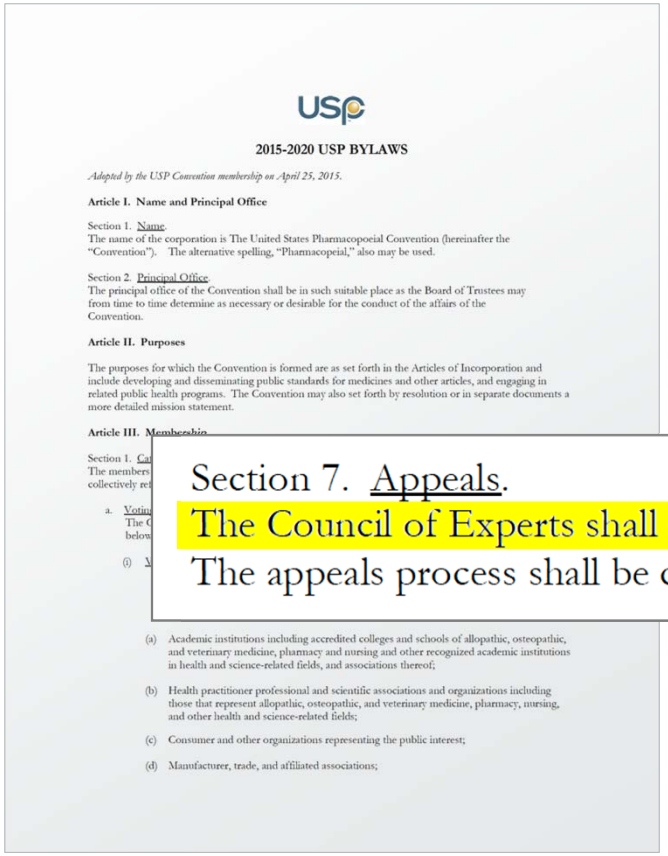
  4. ***Disrupting the entire compounding industry*** and throwing it into upheaval.

- In denying the Coalition's appeal, ***USP did not even purport to address*** these arguments raised by the Coalition (and others).

Roadmap of the Coalition's Appeal

1. Threshold Legal Concerns
2. Problems with USP's Development of the Revised Chapters
3. **Problems with the Adequacy of this Appeal Hearing**
4. Remand to New, Fairly Informed CEC

USP Has Not Issued Formal "Rules and Procedures" for this Appeal



USP

2015-2020 USP BYLAWS

Adopted by the USP Convention membership on April 25, 2015.

Article I. Name and Principal Office

Section 1. Name.
The name of the corporation is The United States Pharmacopoeial Convention (hereinafter the "Convention"). The alternative spelling, "Pharmacopeial," also may be used.

Section 2. Principal Office.
The principal office of the Convention shall be in such suitable place as the Board of Trustees may from time to time determine as necessary or desirable for the conduct of the affairs of the Convention.

Article II. Purposes

The purposes for which the Convention is formed are as set forth in the Articles of Incorporation and include developing and disseminating public standards for medicines and other articles, and engaging in related public health programs. The Convention may also set forth by resolution or in separate documents a more detailed mission statement.

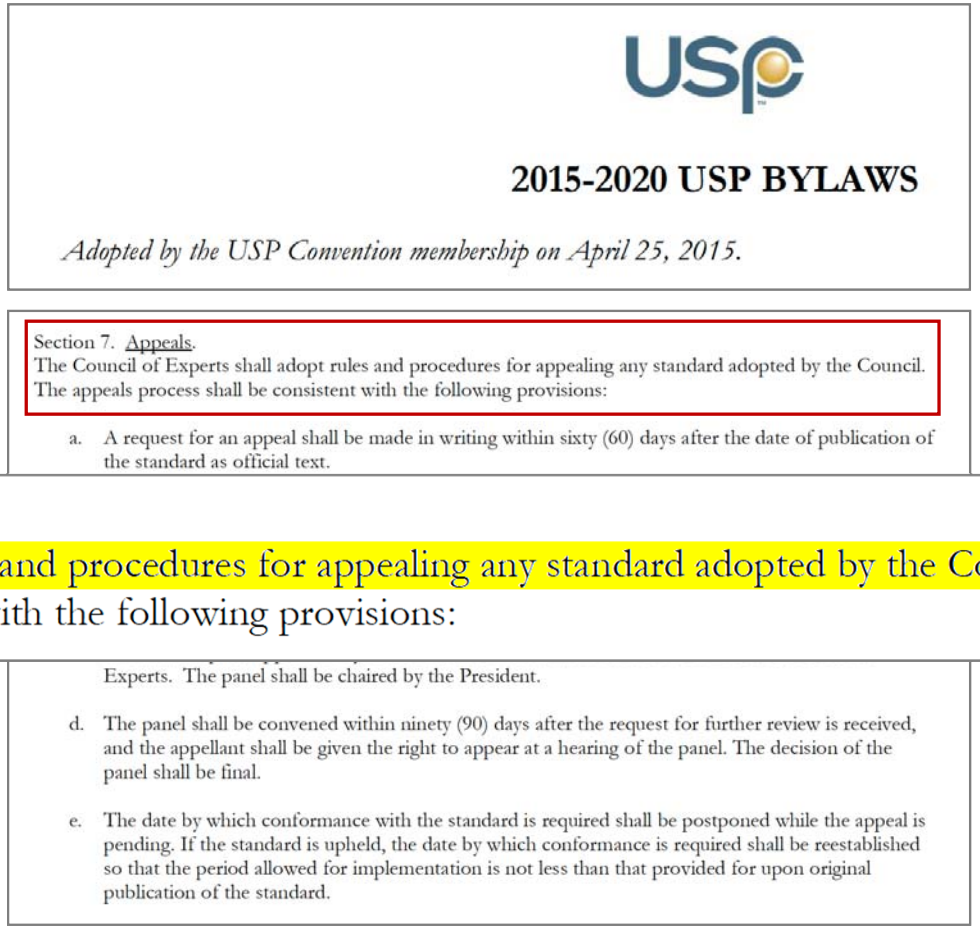
Article III. Membership

(a) Academic institutions including accredited colleges and schools of allopathic, osteopathic, and veterinary medicine, pharmacy and nursing and other recognized academic institutions in health and science-related fields, and associations thereof;

(b) Health practitioner professional and scientific associations and organizations including those that represent allopathic, osteopathic, and veterinary medicine, pharmacy, nursing, and other health and science-related fields;

(c) Consumer and other organizations representing the public interest;

(d) Manufacturer, trade, and affiliated associations;



USP

2015-2020 USP BYLAWS

Adopted by the USP Convention membership on April 25, 2015.

Section 7. Appeals.
The Council of Experts shall adopt rules and procedures for appealing any standard adopted by the Council. The appeals process shall be consistent with the following provisions:

a. A request for an appeal shall be made in writing within sixty (60) days after the date of publication of the standard as official text.

Experts. The panel shall be chaired by the President.

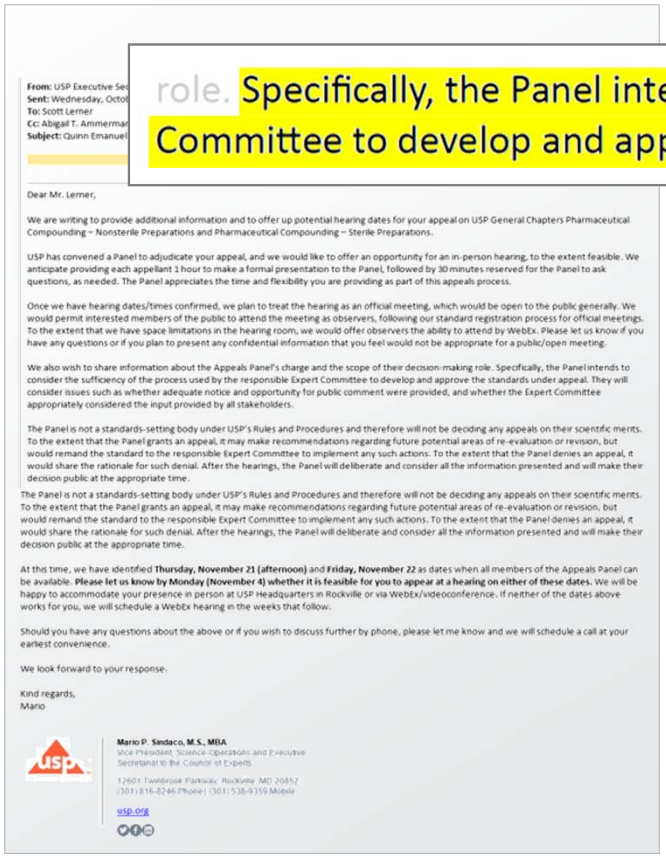
d. The panel shall be convened within ninety (90) days after the request for further review is received, and the appellant shall be given the right to appear at a hearing of the panel. The decision of the panel shall be final.

e. The date by which conformance with the standard is required shall be postponed while the appeal is pending. If the standard is upheld, the date by which conformance is required shall be reestablished so that the period allowed for implementation is not less than that provided for upon original publication of the standard.

Section 7. Appeals.
The Council of Experts shall adopt rules and procedures for appealing any standard adopted by the Council.
The appeals process shall be consistent with the following provisions:

Source Document: 2015-2020 USP Bylaws (adopted April 25, 2015), Art. VII, Sec. 7.

The Panel Is Resolving this Appeal on an Incomplete and Inadequate Record



role. Specifically, the Panel intends to consider the sufficiency of the process used by the responsible Expert Committee to develop and approve the standards under appeal. They will consider issues such as whether

From: USP Executive Se
Sent: Wednesday, Octol
To: Scott Lerner
Cc: Abigail T. Ammermar
Subject: Quinn Emanuel

Dear Mr. Lerner,

We are writing to provide additional information and to offer up potential hearing dates for your appeal on USP General Chapters Pharmaceutical Compounding – Nonsterile Preparations and Pharmaceutical Compounding – Sterile Preparations.

USP has convened a Panel to adjudicate your appeal, and we would like to offer an opportunity for an in-person hearing, to the extent feasible. We anticipate providing each appellant 1 hour to make a formal presentation to the Panel, followed by 30 minutes reserved for the Panel to ask questions, as needed. The Panel appreciates the time and flexibility you are providing as part of this appeals process.

Once we have hearing dates/times confirmed, we plan to treat the hearing as an official meeting, which would be open to the public generally. We would permit interested members of the public to attend the meeting as observers, following our standard registration process for official meetings. To the extent that we have space limitations in the hearing room, we would offer observers the ability to attend by WebEx. Please let us know if you have any questions or if you plan to present any confidential information that you feel would not be appropriate for a public/open meeting.

We also wish to share information about the Appeals Panel's charge and the scope of their decision-making role. Specifically, the Panel intends to consider the sufficiency of the process used by the responsible Expert Committee to develop and approve the standards under appeal. They will consider issues such as whether adequate notice and opportunity for public comment were provided, and whether the Expert Committee appropriately considered the input provided by all stakeholders.

The Panel is not a standards-setting body under USP's Rules and Procedures and therefore will not be deciding any appeals on their scientific merits. To the extent that the Panel grants an appeal, it may make recommendations regarding future potential areas of re-evaluation or revision, but would remand the standard to the responsible Expert Committee to implement any such actions. To the extent that the Panel denies an appeal, it would share the rationale for such denial. After the hearings, the Panel will deliberate and consider all the information presented and will make their decision public at the appropriate time.

The Panel is not a standards-setting body under USP's Rules and Procedures and therefore will not be deciding any appeals on their scientific merits. To the extent that the Panel grants an appeal, it may make recommendations regarding future potential areas of re-evaluation or revision, but would remand the standard to the responsible Expert Committee to implement any such actions. To the extent that the Panel denies an appeal, it would share the rationale for such denial. After the hearings, the Panel will deliberate and consider all the information presented and will make their decision public at the appropriate time.

At this time, we have identified **Thursday, November 21 (afternoon)** and **Friday, November 22** as dates when all members of the Appeals Panel can be available. **Please let us know by Monday (November 4) whether it is feasible for you to appear at a hearing on either of these dates.** We will be happy to accommodate your presence in person at USP Headquarters in Rockville or via WebEx/videoconference. If neither of the dates above works for you, we will schedule a WebEx hearing in the weeks that follow.

Should you have any questions about the above or if you wish to discuss further by phone, please let me know and we will schedule a call at your earliest convenience.

We look forward to your response.

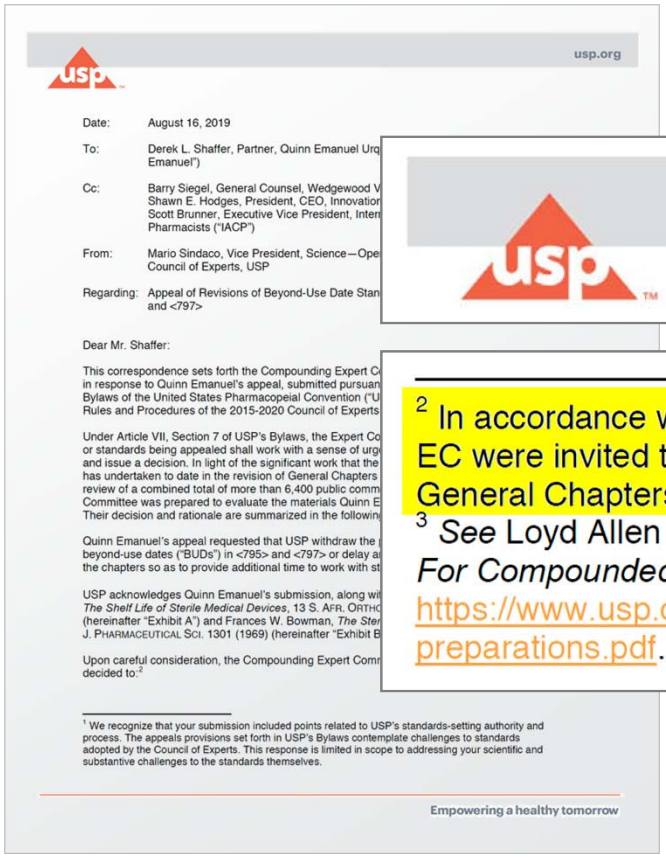
Kind regards,
Mario

Mario P. Sindaco, M.S., MBA
Vice President, Science Operations and Executive Secretariat to the Council of Experts
12601 Twinbrook Parkway, Rockville, MD 20852
(301) 816-8246 Phone | (301) 538-9359 Mobile
usp.org

- Despite purporting to address the "sufficiency of the process," USP has refused to provide the Coalition and this Panel with critical information relevant thereto, including:
  - ***Information concerning known and undisclosed conflicts of interest***;
  - ***Key witness testimony***; and
  - ***Communications with FDA***.
- USP has made it impossible for this Panel to fulfill its mandate.

Source Document: Email from Mario Sindaco to Scott Lerner (Oct. 30, 2019).

The Panel Was Not Permitted to Review Information Related to Conflicts of Interest



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Date: August 16, 2019

To: Derek L. Shaffer, Partner, Quinn Emanuel Urq
Emanuel")

Cc: Barry Siegel, General Counsel, Wedgewood V
Shawn E. Hodges, President, CEO, Innovation
Scott Brunner, Executive Vice President, Inter
Pharmacists ("IACP")

From: Mario Sindaco, Vice President, Science—Ope
Council of Experts, USP

Regarding: Appeal of Revisions of Beyond-Use Date Stan
and <797>

Dear Mr. Shaffer:

This correspondence sets forth the Compounding Expert C
in response to Quinn Emanuel's appeal, submitted pursuan
Bylaws of the United States Pharmacopeial Convention ("U
Rules and Procedures of the 2015-2020 Council of Experts

Under Article VII, Section 7 of USP's Bylaws, the Expert Co
or standards being appealed shall work with a sense of urg
and issue a decision. In light of the significant work that the
has undertaken to date in the revision of General Chapters
review of a combined total of more than 6,400 public comm
Committee was prepared to evaluate the materials Quinn E
Their decision and rationale are summarized in the followin

Quinn Emanuel's appeal requested that USP withdraw the
beyond-use dates ("BUDs") in <795> and <797> or delay a
the chapters so as to provide additional time to work with st

USP acknowledges Quinn Emanuel's submission, along wit
The Shelf Life of Sterile Medical Devices, 13 S. AFR. ORTHO
(hereinafter "Exhibit A") and Frances W. Bowman, *The Ster*
J. PHARMACEUTICAL SCI. 1301 (1969) (hereinafter "Exhibit B

Upon careful consideration, the Compounding Expert Comm
decided to:[2]

[1] We recognize that your submission included points related to USP's standards-setting authority and process. The appeals provisions set forth in USP's Bylaws contemplate challenges to standards adopted by the Council of Experts. This response is limited in scope to addressing your scientific and substantive challenges to the standards themselves.

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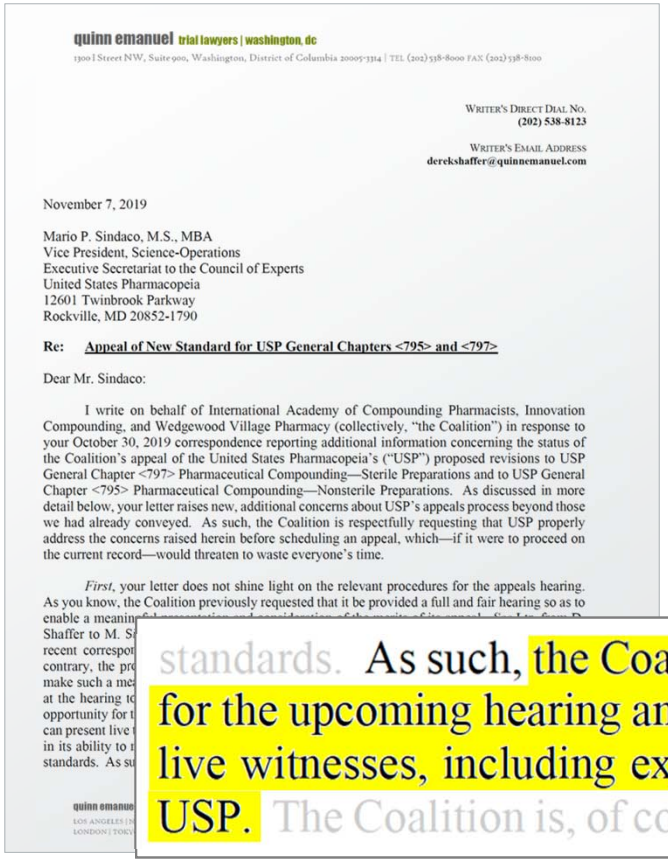
[2] In accordance with USP's rules and policies regarding conflicts of interest, all members of the CMP EC were invited to discuss the appeal. However, members with conflicts of interest related to the General Chapters under appeal recused themselves prior to final discussion and voting.

[3] *See* Loyd Allen Jr, Gus S Bassani, Edmund J Elder Jr, and Alan F Parr, *Strength And Stability Testing For Compounded Preparations*, U.S. PHARMACOPEIAL CONVENTION (Jan. 13, 2014), https://www.usp.org/sites/default/files/usp/document/FAQs/strength-stability-testing-compounded-preparations.pdf.

Source Document: Letter from Mario Sindaco to Derek Shaffer (Aug. 16, 2019).

The Panel Was Not Permitted to Hear Testimony from USP or FDA



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WRITER'S EMAIL ADDRESS
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November 7, 2019

Mario P. Sindaco, M.S., MBA
Vice President, Science-Operations
Executive Secretariat to the Council of Experts
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Appeal of New Standard for USP General Chapters <795> and <797>

Dear Mr. Sindaco:

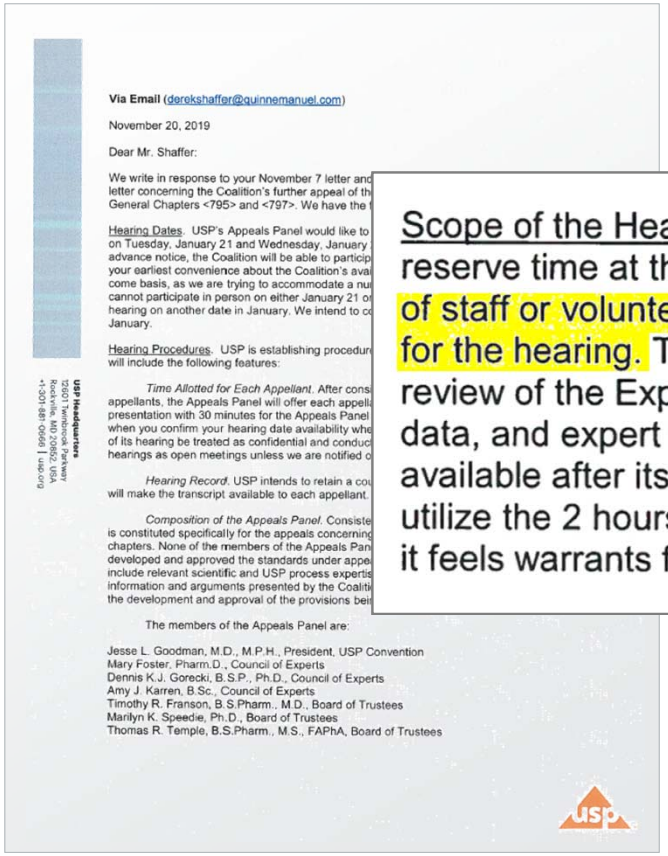
I write on behalf of International Academy of Compounding Pharmacists, Innovation Compounding, and Wedgewood Village Pharmacy (collectively, "the Coalition") in response to your October 30, 2019 correspondence reporting additional information concerning the status of the Coalition's appeal of the United States Pharmacopeia's ("USP") proposed revisions to USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations and to USP General Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations. As discussed in more detail below, your letter raises new, additional concerns about USP's appeals process beyond those we had already conveyed. As such, the Coalition is respectfully requesting that USP properly address the concerns raised herein before scheduling an appeal, which—if it were to proceed on the current record—would threaten to waste everyone's time.

First, your letter does not shine light on the relevant procedures for the appeals hearing. As you know, the Coalition previously requested that it be provided a full and fair hearing so as to enable a meaningful presentation and consideration of the merits of its appeal. *See* Ltr. from D. Shaffer to M. Sindaco, dated Sept. 13, 2019. The appeals process you have described in your recent correspondence, however, affords the Coalition no such rights or protections. To the contrary, the process outlined in your letter appears designed to limit the Coalition's ability to make such a meaningful presentation. For example, USP is limiting the Coalition's participation at the hearing to a mere 1-hour presentation. Such a strict, tight limitation does not afford the opportunity for the Coalition to present and examine witnesses, as we had hoped to do. Unless we can present live testimonial evidence to the Appeals Panel, the Coalition will be severely inhibited in its ability to make a complete record of the procedural and substantive defects in USP's new standards. As such, the Coalition respectfully requests that USP reconsider the current procedures for the upcoming hearing and that it promptly clarify that the Coalition is, in fact, permitted to call live witnesses, including expert witnesses and certain adverse witnesses from or associated with USP. The Coalition is, of course, willing to work with USP (as well as other appellants) to develop a more clear and concrete set of procedures that will allow for an efficient yet fair presentation of all relevant evidence.

standards. As such, the Coalition respectfully requests that USP reconsider the current procedures for the upcoming hearing and that it promptly clarify that the Coalition is, in fact, permitted to call live witnesses, including expert witnesses and certain adverse witnesses from or associated with USP. The Coalition is, of course, willing to work with USP (as well as other appellants) to develop

Source Document: Letter from Derek Shaffer to Mario Sindaco (Nov. 7, 2019).

The Panel Was Not Permitted to Hear Testimony from USP or FDA



Via Email (derekshaffer@quinnemanuel.com)

November 20, 2019

Dear Mr. Shaffer:

We write in response to your November 7 letter and
letter concerning the Coalition's further appeal of th
General Chapters <795> and <797>. We have the

Hearing Dates. USP's Appeals Panel would like to
on Tuesday, January 21 and Wednesday, January
advance notice, the Coalition will be able to particip
your earliest convenience about the Coalition's ava
come basis, as we are trying to accommodate a nu
cannot participate in person on either January 21 o
hearing on another date in January. We intend to c
January.

Hearing Procedures. USP is establishing procedur
will include the following features:

Time Allotted for Each Appellant. After cons
appellants, the Appeals Panel will offer each appell
presentation with 30 minutes for the Appeals Panel
when you confirm your hearing date availability whe
of its hearing be treated as confidential and conduc
hearings as open meetings unless we are notified o

Hearing Record. USP intends to retain a co
will make the transcript available to each appellant.

Composition of the Appeals Panel. Consiste
is constituted specifically for the appeals concernin
chapters. None of the members of the Appeals Pan
developed and approved the standards under appe
include relevant scientific and USP process expertis
information and arguments presented by the Coaliti
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The members of the Appeals Panel are:

Jesse L. Goodman, M.D., M.P.H., President, USP Convention
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Amy J. Karren, B.Sc., Council of Experts
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Thomas R. Temple, B.S.Pharm., M.S., FAPhA, Board of Trustees

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Rockville, MD 20852, USA
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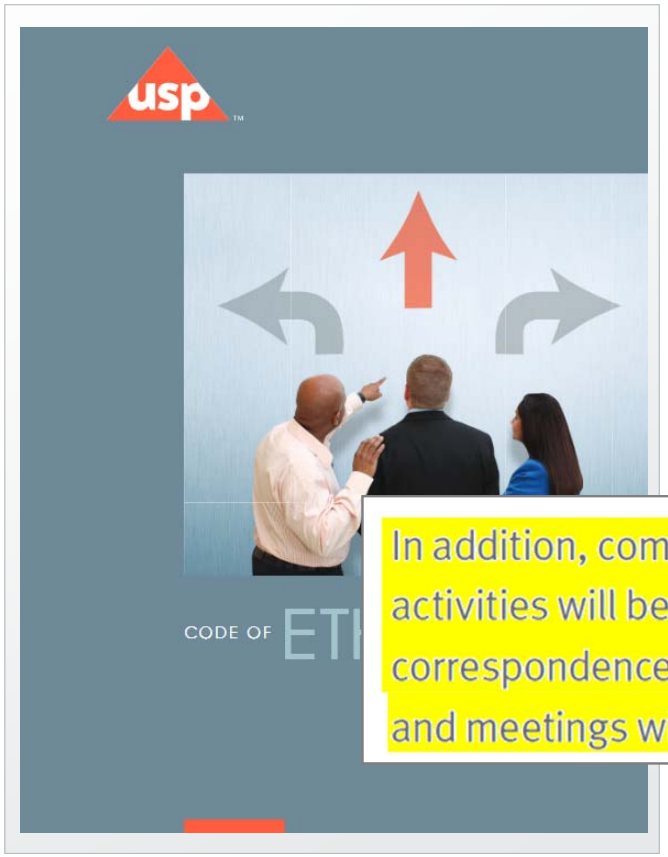
Scope of the Hearing. The hearing is intended to be your opportunity to present. The Panel will reserve time at the end to ask clarifying questions. USP does not intend to make any members of staff or volunteer bodies (e.g., Expert Committee members) available to serve as witnesses for the hearing. The Coalition is free to present any evidence that it feels is relevant to further review of the Expert Committee's decision on the appeal, which may include scientific evidence, data, and expert witness testimony. Further, the Coalition is free to present on information made available after its submission of the original appeal. In short, it is our hope that the Coalition will utilize the 2 hours of hearing presentation time to share any scientific and other information that it feels warrants further review by the Appeals Panel.

Source Document: Letter from Mario Sindaco to Derek Shaffer (Nov. 20, 2019).

The Panel Does Not Have Key Documents Relevant to the Appeal



Document Disclosure

USP provides disclosure of information and records regarding USP standards-setting activities consistent with:

- The rights of individuals to privacy
- USP's need to protect the confidentiality of trade secrets and other proprietary commercial or financial information
- USP's need to promote frank internal deliberations and to pursue standards-setting activities without disruption

Pursuant to this policy, general information pertaining to standards-setting and other activities, including information regarding the work and deliberations of USP's Council of Experts and Expert Committees, is posted and maintained on the USP website.

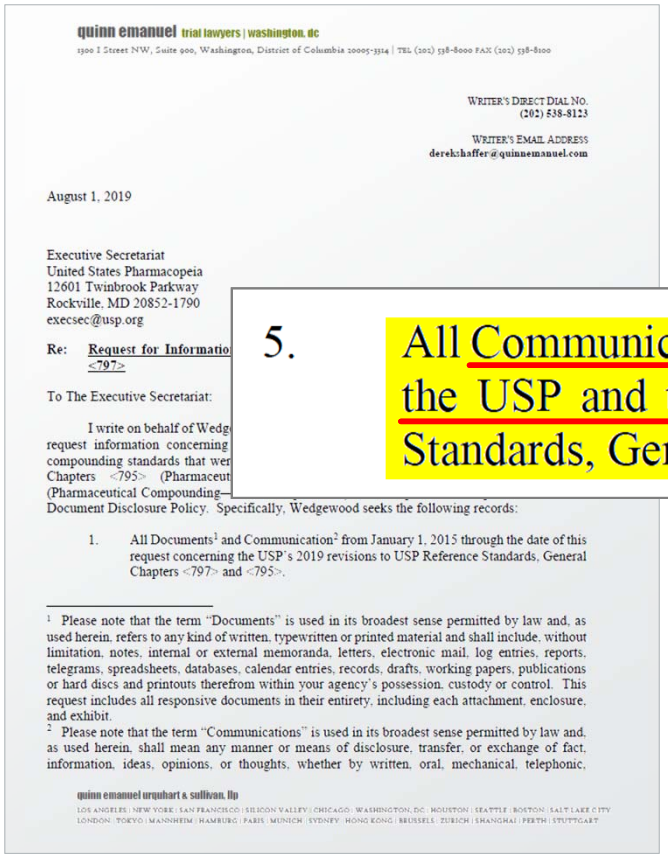
In addition, communications between USP and third parties relating to standards-setting activities will be made available upon specific written request, including copies of written correspondence to and from third parties and memoranda of telephone conversations and meetings with third parties. Such third-party communications do not include communications of any kind among or between USP staff and members of the Board of

In addition, communications between USP and third parties relating to standards-setting activities will be made available upon specific written request, including copies of written correspondence to and from third parties and memoranda of telephone conversations and meetings with third parties. Such third-party communications do not include

All requests for documents shall be made to the USP Executive Secretariat, which shall be responsible for decisions about disclosure of information. A request may be refused solely on the basis that it is unduly burdensome or if USP determines that diversion of personnel from higher-priority duties would be unreasonable.

Source Document: USP Code of Ethics (2015), p.7.

The Panel Does Not Have Key Documents Relevant to the Appeal



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WRITER'S EMAIL ADDRESS
derekshaffer@quinnemanuel.com

August 1, 2019

Executive Secretariat
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790
execsec@usp.org

Re: Request for Informatio
<797>

To The Executive Secretariat:

I write on behalf of Wedg
request information concerning
compounding standards that wer
Chapters <795> (Pharmaceut
(Pharmaceutical Compounding—
Document Disclosure Policy. Specifically, Wedgewood seeks the following records:

1. All Documents[1] and Communication[2] from January 1, 2015 through the date of this request concerning the USP's 2019 revisions to USP Reference Standards, General Chapters <797> and <795>.

[1] Please note that the term "Documents" is used in its broadest sense permitted by law and, as used herein, refers to any kind of written, typewritten or printed material and shall include, without limitation, notes, internal or external memoranda, letters, electronic mail, log entries, reports, telegrams, spreadsheets, databases, calendar entries, records, drafts, working papers, publications or hard discs and printouts therefrom within your agency's possession, custody or control. This request includes all responsive documents in their entirety, including each attachment, enclosure, and exhibit.

[2] Please note that the term "Communications" is used in its broadest sense permitted by law and, as used herein, shall mean any manner or means of disclosure, transfer, or exchange of fact, information, ideas, opinions, or thoughts, whether by written, oral, mechanical, telephonic,

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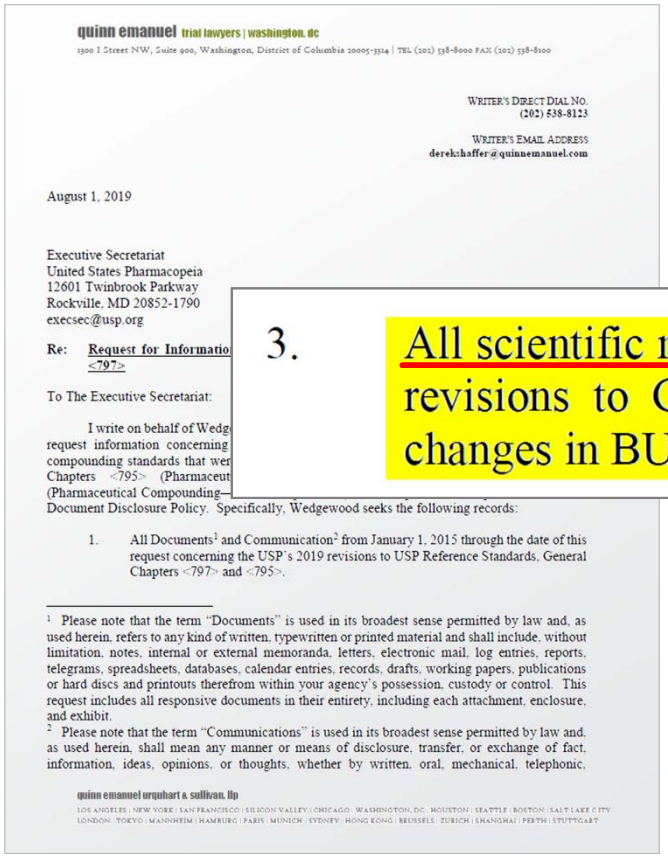
5. All Communications from January 1, 2015 through the date of this request between the USP and the FDA concerning the USP's 2019 revisions to USP Reference Standards, General Chapters <797> and <795>.

Source Document: Letter from Derek Shaffer to USP (Aug. 1, 2019).

The Panel Does Not Have Key Documents Relevant to the Appeal



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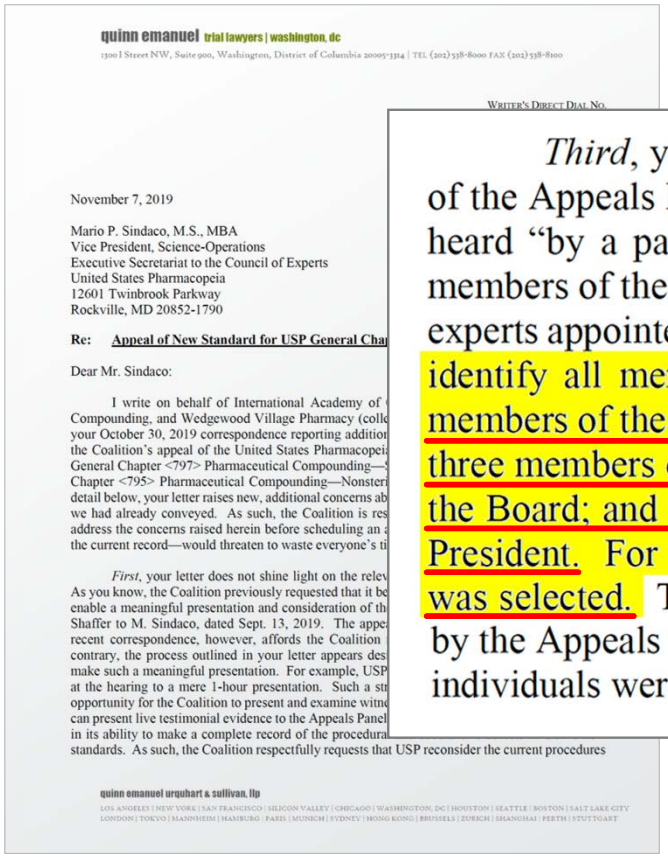
3. All scientific materials or authorities consulted by the USP in connection with the revisions to General Chapters <795> and <797>, particularly with respect to changes in BUD assignment rules.

Source Document: Letter from Derek Shaffer to USP (Aug. 1, 2019).

The Panel Does Not Include Compounding Pharmacy Experts



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November 7, 2019

Mario P. Sindaco, M.S., MBA
Vice President, Science-Operations
Executive Secretariat to the Council of Experts
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Appeal of New Standard for USP General Cha

Dear Mr. Sindaco:

I write on behalf of International Academy of
Compounding, and Wedgewood Village Pharmacy (colle
your October 30, 2019 correspondence reporting additio
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General Chapter <797> Pharmaceutical Compounding—
Chapter <795> Pharmaceutical Compounding—Nonsteri
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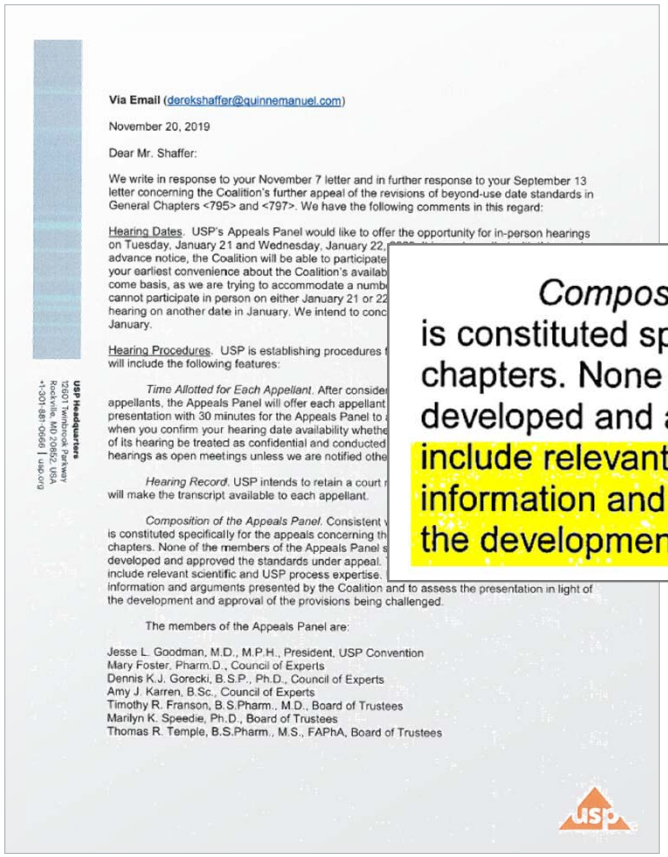
Third, your letter also fails to provide any meaningful information about the composition of the Appeals Panel. Article VII, Section 7(c) of the USP Bylaws states that all appeals will be heard "by a panel of three members of the Council of Experts appointed by the Chair, three members of the Board of Trustees appointed by the Chair of the Board, and up to three additional experts appointed by the President in consultation with the Chair of the Council of Expert." Please identify all members of the Appeals Panel, including by specifically identifying (i) the three members of the Council of Experts who were appointed to the Appeals Panel by the Chair; (ii) the three members of the Board of Trustees who were appointed to the Appeals Panel by the Chair of the Board; and (iii) any additional experts who were appointed to the Appeals Panel by the USP President. For each Panel member selected by USP, please explain how and why each member was selected. To state the obvious, composition of the Appeals Panel directly affects resolution by the Appeals Panel. The Coalition wants to know whom it's appealing to and how the relevant individuals were appointed before arguing its case.

Source Document: Letter from Derek Shaffer to Mario Sindaco (Nov. 7, 2019).

The Panel Does Not Include Compounding Pharmacy Experts



Via Email (derekshaffer@quinnemanuel.com)

November 20, 2019

Dear Mr. Shaffer:

We write in response to your November 7 letter and in further response to your September 13 letter concerning the Coalition's further appeal of the revisions of beyond-use date standards in General Chapters <795> and <797>. We have the following comments in this regard:

Hearing Dates. USP's Appeals Panel would like to offer the opportunity for in-person hearings on Tuesday, January 21 and Wednesday, January 22, [illegible] advance notice, the Coalition will be able to participate [illegible] your earliest convenience about the Coalition's availab [illegible] come basis, as we are trying to accommodate a numb [illegible] cannot participate in person on either January 21 or 22 [illegible] hearing on another date in January. We intend to conc [illegible] January.

Hearing Procedures. USP is establishing procedures [illegible] will include the following features:

Time Allotted for Each Appellant. After consider [illegible] appellants, the Appeals Panel will offer each appellant [illegible] presentation with 30 minutes for the Appeals Panel to [illegible] when you confirm your hearing date availability whethe [illegible] of its hearing be treated as confidential and conducted [illegible] hearings as open meetings unless we are notified othe [illegible]

Hearing Record. USP intends to retain a court [illegible] will make the transcript available to each appellant.

Composition of the Appeals Panel. Consistent [illegible] is constituted specifically for the appeals concerning th [illegible] chapters. None of the members of the Appeals Panel s [illegible] developed and approved the standards under appeal. [illegible] include relevant scientific and USP process expertise. [illegible] information and arguments presented by the Coalition and to assess the presentation in light of the development and approval of the provisions being challenged.

The members of the Appeals Panel are:

Jesse L. Goodman, M.D., M.P.H., President, USP Convention
Mary Foster, Pharm.D., Council of Experts
Dennis K.J. Gorecki, B.S.P., Ph.D., Council of Experts
Amy J. Karren, B.Sc., Council of Experts
Timothy R. Franson, B.S.Pharm., M.D., Board of Trustees
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Thomas R. Temple, B.S.Pharm., M.S., FAPhA, Board of Trustees

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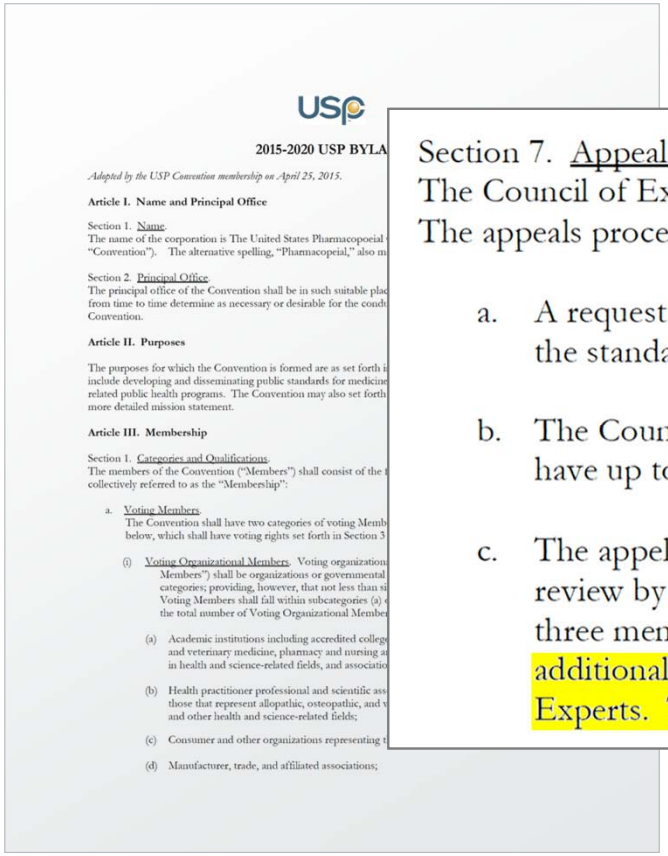
Composition of the Appeals Panel. Consistent with the USP Bylaws, the Appeals Panel is constituted specifically for the appeals concerning the proposed revisions to the compounding chapters. None of the members of the Appeals Panel served on the Expert Committee that developed and approved the standards under appeal. The Appeals Panel was selected to include relevant scientific and USP process expertise. It will be well-positioned to evaluate information and arguments presented by the Coalition and to assess the presentation in light of the development and approval of the provisions being challenged.

Source Document: Letter from Mario Sindaco to Derek Shaffer (Nov. 20, 2019).

The Panel Does Not Include Compounding Pharmacy Experts



2015-2020 USP BYLA

Adopted by the USP Convention membership on April 25, 2015.

Article I. Name and Principal Office

Section 1. Name.
The name of the corporation is The United States Pharmacopoeial
"Convention"). The alternative spelling, "Pharmacopeial," also m

Section 2. Principal Office.
The principal office of the Convention shall be in such suitable plac
from time to time determine as necessary or desirable for the condu
Convention.

Article II. Purposes

The purposes for which the Convention is formed are as set forth i
include developing and disseminating public standards for medicine
related public health programs. The Convention may also set forth
more detailed mission statement.

Article III. Membership

Section 1. Categories and Qualifications.
The members of the Convention ("Members") shall consist of the
collectively referred to as the "Membership":

a. Voting Members.
The Convention shall have two categories of voting Memb
below, which shall have voting rights set forth in Section 3

(i) Voting Organizational Members. Voting organization
Members") shall be organizations or governmental
categories; providing, however, that not less than si
Voting Members shall fall within subcategories (a)
the total number of Voting Organizational Member

(a) Academic institutions including accredited colleg
and veterinary medicine, pharmacy and nursing a
in health and science-related fields, and associatio

(b) Health practitioner professional and scientific ass
those that represent allopathic, osteopathic, and
and other health and science-related fields;

(c) Consumer and other organizations representing

(d) Manufacturer, trade, and affiliated associations;

Section 7. Appeals.
The Council of Experts shall adopt rules and procedures for appealing any standard adopted by the Council. The appeals process shall be consistent with the following provisions:

a. A request for an appeal shall be made in writing within sixty (60) days after the date of publication of the standard as official text.

b. The Council or Expert Committee establishing the standard shall work with a sense of urgency and have up to ninety (90) days to reconsider the standard and issue a decision.

c. The appellant shall have thirty (30) days following receipt of the decision to request in writing further review by a panel consisting of three members of the Council of Experts appointed by the Chair, three members of the Board of Trustees appointed by the Chair of the Board, and up to three additional experts appointed by the President in consultation with the Chair of the Council of Experts. The panel shall be chaired by the President.

Source Document: 2015-2020 USP Bylaws (adopted April 25, 2015), Art. VII, Sec. 7(c).

In Addition to No Subject Matter Experts, the Panel Is Not Fully Assembled

- Seven members on the Appeals Panel;
- Two not present today;
- One Panel Member, Tim Franson, is not participating in today's hearing; and
- Another Panel Member, Mary Foster, is participating remotely.

Roadmap of the Coalition's Appeal

1. Threshold Legal Concerns
2. Problems with USP's Development of the Revised Chapters
3. Problems with the Adequacy of this Appeal Hearing
4. **Remand to New, Fairly Informed CEC**

Conclusion

Where Do We Go from Here?

- Cannot defer to “expertise” of prior CEC on the current record;
- Remand to newly constituted CEC that is fairly informed; and
- Start anew with full transparency and public participation.

Questions?