



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE: January 19, 2016

LOCATION: Department of Consumer Affairs
1st Floor Hearing Room
1625 North Market Blvd.
Sacramento, Ca 95834

BOARD MEMBERS

PRESENT: Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Stanley Weisser, RPh
Gregory Lippe, Public Member
Allen Schaad, RPh
Ramon Castellblanch, Public Member
Albert Wong, PharmD

BOARD MEMBERS

NOT PRESENT: Lavanza Butler, RPh
Rosalyn Hackworth, Public Member
Ryan Brooks, Public Member
Ricardo Sanchez, Public Member
Gregory Murphy, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Joshua Room, Supervising Deputy Attorney General
Laura Hendricks, Staff Analyst
Lori Martinez, Staff Manager

Note: The webcast of this meeting may be found at:

<http://www.pharmacy.ca.gov/about/meetings.shtml>

Tuesday, January 19, 2016

Call to Order

9:06 a.m.

I. Call to Order, Establishment of Quorum and General Announcements

President Gutierrez called the meeting to order at 9:06 a.m. Board members present: Stanley Weisser, Amy Gutierrez, Victor Law, Albert Wong, Deborah Veale, Ricardo Sanchez and Greg Lippe.

Note: Allen Schaad arrived at 9:15 a.m. and Ramon Castellblanch arrived at 9:35 a.m.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

There were no comments from the board or from the public.

III. Petitions for Reinstatement of Licensure or Other Reduction of Penalty

Administrative Law Judge Karen Brandt presided over the petition for reinstatement of licensure for Keith Chung, RPH 50486.

The board recessed for a break at 10:06 a.m. and resumed at 10:15 a.m.

Administrative Law Judge Karen Brandt presided over the petition for reinstatement of licensure for Erin Rodrick (Maloney), RPH 46916,

IV. Closed Session

Pursuant to Government Code Section 11126(c)(3), the Board convened closed session at 11:00 a.m. to deliberate on the petitions for reinstatement of licensure.

V. Reconvene Open Session

The board reconvened open session at 12:42 p.m.

VI. Regulations

a. Board Approved – Notice Period Pending or Completed

1. Proposed Regulations to Amend Title 16 California Code of Regulations (CCR) Sections 1715 and 1784 related to Self-Assessment Forms 17M-13, 17M-14, and 17M-26

Chairperson Lippe reported that on March 20, 2015, the board initiated a formal rulemaking process to amend the text of 16 California Code of Regulations sections 1715 and 1784 and to amend the Self-Assessment Forms incorporated by

reference therein. Existing regulation requires a pharmacy, wholesaler and hospital to complete a self-assessment by July 1 of each odd-numbered year, and at other times, as specified in the regulation(s).

Chairperson Lippe stated that the rulemaking was open for two 45-day comment periods: the first from March 20 to May 6, 2015 – and then from May 29 through July 13, 2015. Thereafter, in November 2015, board staff compiled the final rulemaking documents and submitted the file to the Office of Administrative Law to begin the administrative review process.

Chairperson Lippe reported that the Office of Administrative Law returned the rulemaking to the board for the purpose of reviewing a comment on the Hospital Pharmacy Self-Assessment. Specifically, the board was asked to determine if the self-assessment form should be modified to explain or further clarify what “personally registered with the federal Drug Enforcement Administration” means.

Chairperson Lippe explained that board staff determined this was a non-substantive issue and that clarification was not required; however, the Office of Administrative law requested that the board consider the comment before completing its review of the rulemaking record.

Note: The comments received were provided in the board meeting materials.

Ms. Herold explained that when a pharmacist prescribes a controlled substance they are required to have a DEA number.

Mr. Law stated that he had been informed that pharmacists would not be issued DEA numbers. Ms. Herold responded that pharmacists *are* issued mid-level practitioner DEA numbers. President Gutierrez and Mr. Schaad added that the DEA website states that pharmacists are issued DEA numbers.

Dr. Steve Gray, from Kaiser Permanente, confirmed that pharmacists are registered with the DEA as mid-level practitioners.

Ms. Freedman explained that the board must determine if the self-assessment form needs to be modified in response to the comments received. She added that the staff recommendation is to not modify the language.

As pharmacists must have DEA numbers in order to prescribe controlled substances, the board determined that the phrase “personally registered with the federal Drug Enforcement Administration” was appropriate and should remain in the self-assessment.

Motion: Adopt the noticed regulatory language, and delegate to the executive officer the authority to make technical or non-substantive changes as may be

required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

M/S: Weisser/Veale

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

2. Proposed Regulations to Add Title 16 CCR sections 1730 and 1730.1 related to Advanced Practice Pharmacists

Chairperson Lippe reported that in June 2015, staff initiated a formal rulemaking to add Section 1730 to Title 16 of the California Code of Regulations related to Advanced Practice Pharmacist. Following the 45-day comment period, the board modified the proposed text and thereafter, from October 9-23, 2015, issued a 15-day public comment period. He noted that a second 15-day public comment was initiated from November 20-December 5, 2015.

Chairperson Lippe explained that at this meeting, the board will consider comments received during the 15-day comment period that closed on December 5.

Note: The comments received were provided in the board meeting materials.

Staff reviewed the three comments received during the 15-day comment period. Staff noted that the comments could be rejected by the board as they were outside of the scope of the comment period. The board elected not to amend the regulation in response to the comments received during the 15-day comment period.

Ms. Herold explained that pharmacist Douglas Barcon was unable to attend the board meeting and asked staff to provide his comments to the board in the form of a letter. The letter from Dr. Barcon is provided immediate following these

minutes.

The board discussed the recommended changes to the regulation language that Dr. Barcon provided in his letter. However, the board elected not to further amend the regulation language in response to Dr. Barcon’s written comments.

President Gutierrez stated that it is important for the board to move forward with the regulation. She added that in the future the board can modify the language in response to any issues that may arise.

Ms. Herold explained that all of the SB 493 regulations will become effective immediately upon filing with the Secretary of State.

Motion: Adopt the noticed regulatory language, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

M/S: Weisser/Veale

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

3. Proposed Regulations to Add Title 16 CCR section 1746.1 related to Self-Administered Hormonal Contraception

Chairperson Lippe reported that in May 2015, the board initiated a formal rulemaking to add Title 16 California Code of Regulations section 1746.1 related to Self-Administered Hormonal Contraception. The 45-day comment period concluded on June 22, 2016, and the board approved the final language at the September 2015 Board Meeting.

Chairperson Lippe stated that board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process on October 13, 2015. On December 30, 2015, a 15-day comment period began to add several documents to the rulemaking file and to revise the economic impact assessment within the Initial Notice documents. The comment period closed January 14, 2016.

Note: A copy of the one comment received during the 15-day comment period was provided in the meeting materials.

The board reviewed the comment received during the 45 day comment period, which stated that pharmacists should not be allowed to dispense hormonal contraception without a prescription because of the unnecessary hardship it will place on the pharmacist. The board rejected the comment as it was outside of the scope of the comment period and contradicted the statute.

Ms. Herold noted that this regulation will become effective immediately upon its completed review and filing with the Secretary of State.

Motion: Adopt the proposed regulatory changes as noticed, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Weisser/Gutierrez

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

4. Proposed Regulations to Add Title 16 CCR section 1746.5 related to Travel Medications

Chairperson Lippe reported that on September 25, 2015, the board initiated a formal rulemaking to add Title 16 California Code of Regulations Section 1746.5 related to Travel Medications. He added that the 45-day comment period closed on November 9, 2015.

Chairperson Lippe explained that at this meeting, the board will consider the comments received during the 45-day public comment period.

Note: The comments received during the comment period were provided in the board meeting materials.

The board reviewed the comments submitted by Scott Clark during the 45-day comment period. After discussion, Mr. Clark's comments were rejected by the board.

The board reviewed the comments submitted by Brian Warren, Mary Staples and Angie Manetti. Mr. Warren clarified the comments he submitted during the comment period. He suggested modifying the language as follows.

- (c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:
- (1) Completion of an immunization certificate program that meets the requirements of Section 1746.4,
 - (2) Completion of a approved travel medicine training program, which must consist of at least 10 20 hours of training and cover each relevant elements of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine (2012),
 - ~~(2)~~ (3) Completion of the CDC Yellow Fever Vaccine Course, and
 - ~~(3)~~ (4) Current basic life support certification.

The board noted that the comments submitted by Dr. Jeff Goad were similar to those submitted by Mr. Warren (above); the only difference a variation in the wording. The board elected to use the language provided by Mr. Warren as it better clarified the training requirements and still achieved the intended outcome of Dr. Goad's proposed language.

DCA counsel Laura Freedman, cautioned the board that removing the word "each" and replacing it with "relevant" could cause problems with getting the regulation approved by the Office of Administrative Law (OAL). She explained that the term relevant is ambiguous. In response to Ms. Freedman's statement the board amended the language as follows.

- (c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:
- (1) Completion of an immunization certificate program that meets the requirements of Section 1746.4,
 - (2) Completion of a approved travel medicine training program, which must consist of at least 10 20 hours of training and cover each relevant medication related elements of

the International Society of Travel Medicine’s Body of Knowledge for the Practice of Travel Medicine (2012),

~~(2)~~ (3) Completion of the CDC Yellow Fever Vaccine Course, and

~~(3)~~ (4) Current basic life support certification.

President Gutierrez asked if the board should remove the year “2012” from the language as provided below.

...elements of the International Society of Travel Medicine’s Body of Knowledge for the Practice of Travel Medicine ~~(2012)~~.

Ms. Freedman explained that per OAL, the year must remain in the regulation. Staff noted that upon initial review of the language, OAL specifically stated that the year must be provided.

The board discussed Dr. Goad’s suggestion to remove the primary care provider reporting requirement. Supervising Deputy Attorney General Joshua Room, explained that the reporting requirement is in statute so it cannot be removed.

The board elected to update the language so that the term “furnished” is used consistently throughout the regulation.

Motion: Modify the regulation language as provided below. Initiate a 15-day comment period.

Proposed Text

Add §1746.5 to Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1746.5 Pharmacists Furnishing Travel Medications.

- (a) For purposes of Business and Professions Code section 4052(a)(10)(A)(3), prescription medications “not requiring a diagnosis” means a prescription medication that is either:
 - (1) For a condition that is both self-diagnosable and recognized as self-treatable by the federal Center for Disease Control and Prevention’s (CDC) Health Information for International Travel (commonly called the Yellow Book), or
 - (2) A prophylactic.
- (b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to section 4052(a)(10) of the Business and Professions Code shall follow the requirements of this section.
- (c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:
 - (1) Completion of an immunization certificate program that meets the requirements of Section 1746.4,
 - (2) Completion of a an-approved travel medicine training program, which must consist of at least 10 20 hours of training and cover each-medication related elements of the International Society of Travel Medicine’s Body of Knowledge for the Practice of Travel Medicine (2012),

- ~~(2)~~ (3) Completion of the CDC Yellow Fever Vaccine Course, and
- ~~(3)~~ (4) Current basic life support certification.

- (d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.
- (e) Prior to furnishing travel medication, a pharmacist shall perform a good faith evaluation of the patient, including evaluation of a patient travel history using destination-specific travel criteria. The travel history must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history is available on the Board’s website.
- (f) Notifications: The pharmacist shall notify the patient’s primary care provider of any drugs and/or devices furnished to the patient within 30 days of the date of **dispense furnishing**, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient’s choice.
- (g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic manner such that the information required by title 42, section 300aa-25 of the United States Code and title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility’s normal operating hours. A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel medication plan. An example of an appropriate and comprehensive progress note is available on the Board’s website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052, Business and Professions Code.

M/S: Gutierrez/Weisser

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Butler				X
Castellblanch	X			
Gutierrez	X			
Law	X			
Lippe	X			
Murphy				X
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			

Wong	x			
------	---	--	--	--

Motion: If no comments are received during the 15-day comment period, delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Gutierrez/Lippe

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

5. Proposed Regulations to Add Title 16 CCR section 1746.4 related to Vaccinations

Chairperson Lippe reported that on July 24, 2015, the board initiated a formal rulemaking to add Title 16 California Code of Regulations section 1746.4 related to Vaccinations. The 45-day comment period concluded on September 7, 2015.

Chairperson Lippe explained that in response to the comments received, the board approved modifications to the language and thereafter issued modified text for a 15-day comment period. Following the review of comments received, the board again modified the text of the regulation and issued a second 15-day comment period from November 20 through December 5, 2015.

Note: The comments received during the 15-day public comment period that closed on December 15 were provided in the board meeting materials.

Staff explained that the two comments received both objected to pharmacists being required to report immunizations into the national registry. Additionally, one of the commenters asked the board to consider allowing entities to receive waivers from the reporting requirement. The board rejected the comments.

Staff noted that one of the commenters also asked the board to remove the requirement for pharmacists to report immunizations to primary care doctors. The board rejected this comment.

Motion: Adopt the proposed regulatory changes as noticed, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Weisser/Veale

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Ms. Herold noted that this regulation will become effective immediately upon its completed review and filing with the Secretary of State.

President Gutierrez stated that the board’s website is being updated to make the status each pending regulation clearer to interested parties.

6. Proposed Regulations to Amend Title 16 CCR sections 1735 et seq., and 1751 et seq., Relating to Compounding

Chairperson Lippe reported that on May 8, 2015, the board initiated a formal rulemaking related to compounding. The 45-day comment period concluded on June 22, 2015. The board held a regulation hearing on June 25, 2015.

Chairperson Lippe stated that at the July 2015 Board Meeting, the board reviewed the 45-day comments received and modified the language of the rulemaking. A 15-day comment period ran from July 31 through August 15, 2015. Thereafter, at the October Board Meeting, the board reviewed the comments and again approved modified language for public comment. Chairperson Lippe reported that a second 15-day comment period concluded on December 5.

Note: The comments received during the second 15-day comment period were provided in the board meeting materials.

Chairperson Lippe explained that at this meeting, the board will review the regulation; the comments received and determine whether or not to adopt the language approved in October, or make further modifications and initiate another comment period.

Supervising Inspector Michael Ignacio explained that the last 15-day comment period was limited to typographical errors and language clarification. Mr. Room explained that staff reviewed the comments received during the comment period and does not recommend modifying the language in response to the comments.

Dr. Ignacio reported that board staff worked with President Gutierrez, Mr. Schaad and legal counsel to make clarification and typographical changes to improve the language. President Gutierrez noted that all the modifications made by staff were non-substantive and would not require the board to initiate another 15-day comment period.

President Gutierrez and Mr. Schaad stated that they would recommend approving the regulation (with the non-substantive changes provided by staff) so that the board inspectors can begin enforcing the new regulations and improve patient safety. President Gutierrez added that the regulations would need to be updated on an ongoing basis as the practice of compounding is always evolving.

Ms. Freedman recommended that the board adopt the regulation as noticed, without the non-substantive changes made by board staff. She explained that the board could delegate the authority to the executive officer to make non-substantive changes to the language. Ms. Freedman stated this would make for a cleaner rulemaking file and would still achieve the board's intent to incorporate the non-substantive changes provided by staff.

Motion: Adopt the proposed regulatory changes as noticed, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Weisser/Sanchez

Brian Warren, CPhA, asked the board to consider modifying 1751.7(e). He recommend modifying subparagraph (B) of paragraph (2) to allow for a 14-day course of therapy, as testing for sterility and pyrogens takes up to 14 days to complete. The board did not modify the language based on Mr. Warren's comment.

Mr. Warren also asked the board to modify 1751.7(e)(1) because as written it would eliminate alternative sterility testing methodologies. Dr. Ignacio stated that the comments related to alternative testing methodologies were reviewed and it was

determined that as the testing methodologies have not been approved by the FDA, the language should not be modified.

Dr. Navid Vahedi and Dr. Eric Feinstein, representing Fusion Rx, stated that they had an alternative testing method called ScanRDI®. Dr. Vahedi asked the board to modify the language to allow the use of alternative testing methodologies.

The board recessed for a break at 2:20 p.m. to set-up a presentation on ScanRDI® and resumed at 2:30p.m.

Dr. Feinstein provided a presentation on the testing methodologies used by ScanRDI®.

Note: the materials presented to the board by Dr. Navid Vahedi and Dr. Eric Feinstein are provided immediately following these minutes.

The board asked if ScanRDI® is approved by the FDA. Dr. Feinstein stated that it has been assigned a “Drug Master File Number (DMF)” by the FDA. President Gutierrez responded that according to the FDA a DMF is assigned to documents submitted to the FDA, it does not mean it has been approved by the FDA.

Mr. Schaad stated that in order for the board to modify the language to allow alternative testing methodologies, the board needs to have proof that the FDA has approved this new technology.

Dr. Vahedi asked the board not to approve the compounding regulation until they have had time to obtain documentation of approval from the FDA.

Supervising Inspector Christine Acosta expressed concern regarding the use of ScanRDI® and recommended that the board not modify the language in response to the request by Dr. Vahedi and Dr. Feinstein.

Ms. Herold asked if Fusion Rx is registered with the FDA as an outsourcing facility. Dr. Vahedi responded that they are planning on becoming registered in the future.

Ms. Herold recommended to the board that they move forward with the compounding regulation. She added that if Fusion Rx can provide a letter from the FDA stating that the testing has been approved for use, then the board can consider pulling back the regulation and start another proceeding. Ms. Herold explained that the regulation would have to be updated in the future as the practice of compounding changes (i.e. implementation of USP 800).

Mr. Weisser and agreed that the board should move forward with the regulation and not delay it while the board awaited the approval documentation from the FDA. The board decided to vote on the motion previously made by Mr. Weisser and Mr. Sanchez to move the regulation forward.

Motion: Adopt the proposed regulatory changes as noticed, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Weisser/Sanchez

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

b. Awaiting Notice

1. Proposed Regulations to Add Title 16 CCR sections 1776 et seq., related to Drug Take-Back.

Chairperson Lippe explained that at the October 2015 Board Meeting, the board approved proposed text to add Sections 1776 et seq. to Title 16 of the California Code of Regulations related to Drug Take-Back with specific modifications.

Chairperson Lippe stated that the modified proposed text has been provided in the board meeting materials and would be discussed at today’s meeting.

Ms. Herold explained that the text was modified at the request of the board to change the liner requirements. She stated that the liner changes resulted in a significant re-numbering of the language, so out of an abundance of caution the language is being brought back to the board for re-approval.

Dr. Castellblanch expressed concern that the modified language was not provided to the public in a timely manner. Mr. Room noted that if the board approved the language it would move to comment period, and interested parties would have 45-days to review the language and submit comments. Ms. Herold added that the board has discussed drug-take back programs and presented draft language at

several meetings over the past year. She recommended officially beginning the regulation process so stakeholders can submit comments for the record.

Staff noted that Tim Goncharoff, of Santa Cruz, was unable to attend the meeting and submitted written comments. The comments were provided to the board and to the public. The comments have been provided immediately following these minutes.

President Gutierrez recommended modifying the language to clarify that only the physical take-back receptacle would be voluntary, counties could still mandate the use of mail-back envelopes.

Dr. Castellblanch stated that we would like board to modify the language to state that take-back programs are voluntary unless required by local or federal law.

Mr. Weisser stated that the board needs to decide how much an entity other than the Pharmacy Board should be able to regulate what occurs in a pharmacy.

Ms. Veale stated that she would not like counties to mandate the use of mail-back envelopes as they place an undue financial burden on pharmacies.

President Gutierrez reminded the board members that it is the Board of Pharmacy's mandate to protect consumers, and the regulations should focus on how to safely implement take-back programs.

Mr. Weisser stated that pharmacy staff should be focused on giving patients healthcare advice, and expressed concerned that mandating take-back programs will take way a pharmacist's time with a patient. Dr. Castellblanch reported that he visited a pharmacy that participates in a take-back program, and the pharmacist stated that maintaining the bin takes approximately 20 minutes per week.

Dr. Castellblanch stated that the board needs to address the opioid abuse epidemic and the safe disposal of unused medications is an important step in that process.

President Gutierrez stated that a pharmacist-in-charge should not be required to place a take-back receptacle in their pharmacy if they do not feel that they can safely operate it. She added that if a county wants to mandate a take-back program and the pharmacy does not want to host a receptacle, then the pharmacy should use the mail-back program to comply with the county ordinance.

President Gutierrez reported that statistics show that only eight out of every 100 mail-back envelopes actually are used by consumers. Dr. Castellblanch responded that he would consider the use of eight out of 100 envelopes a success. Ms. Veale reminded that board that the even though only eight envelopes were used, the pharmacy still had to pay for all 100 envelopes. Dr. Wong agreed that the envelopes may be too expensive for some pharmacies to provide.

Ms. Veale stated that take-back programs (both mail-back and physical receptacles) should be voluntary.

Mr. Lippe stated that pharmacies may want to participate because hosting a receptacle will bring more customers into the pharmacy.

Mr. Law explained pharmacies should be allowed to decide if they can safely operate a take-back receptacle, as in some neighborhoods a receptacle may attract drug addicts and increase burglaries.

Dr. Castellblanch asked legal counsel if the board has the authority to preempt county ordinances.

Mr. Room stated the board clearly has the authority to regulate how licensees participate in take-back programs. However, there is not a clear answer as to whether the board's regulation would preempt county ordinances. Mr. Room recommended that the board clearly state if it intends to preempt county ordinances or if it wants to allow counties to mandate programs. Ms. Freedman agreed and added that counties could bring the preemption issue to court and it would be decided by the court if the board's regulation preempts county ordinances.

Mr. Law and Dr. Wong stated that small community pharmacies may have financial difficulty participating in a mandatory take-back program. President Gutierrez stated that in Alameda County drug manufacturers fund the take-back programs.

Heidi Sanborn, Executive Director of the California Product Stewardship Council, explained that there are two types of take-back programs, those that are funded by the pharmacies and those that are funded by the drug manufacturers. She added that in most other countries the take-back programs are funded by drug manufacturers.

Mr. Weisser stated that small pharmacies may have difficulty finding room for the receptacles. Ms. Sanborn responded that there are receptacles of varying sizes.

Ms. Veale asked Ms. Sanborn if the California Product Stewardship Council would support voluntary or mandated programs. Ms. Sanborn responded that they have always supported voluntary programs. However, she noted that they are very concerned with the board preempting counties who have decided it is in the best interest of the public health to mandate take-back programs.

Ms. Sanborn recommended the board proceed with the regulations so that stakeholders could submit written comments for the record.

Mr. Schaad asked if pharmacies can accept controlled substances. Ms. Herold responded that the pharmacy must register with the DEA in order to take back controlled substances. President Gutierrez added that patients do not know the difference between controlled and non-controlled medications and will therefore place all of them in the bin.

President Gutierrez recommended changing section 1776.3 to allow the pharmacist-in-charge to refuse installation of a take-back receptacle if in his or her professional opinion; it cannot be operated in a safe manner. Ms. Veale agreed that receptacles may not be appropriate for some pharmacies and the pharmacist-in-charge should have the ability to make that determination.

President Gutierrez recommended changing section 1776.3(b) to require the receptacles be locked when the pharmacy is closed.

President Gutierrez also recommended requiring that the receptacle be physically blocked when the pharmacy is closed. She clarified that in big-box stores the pharmacy may be closed while the rest of the store is still opened. Physically blocking the receptacle would prevent customers from placing items on top of the receptacle.

Dr. Castellblanch asked if the receptacles could be placed behind the pharmacy counter. Ms. Herold explained that the DEA requirements would not allow this.

Ms. Herold recommended the board focus on creating requirements for safely operating a take-back receptacle. She added that if a pharmacy cannot meet the requirements for the receptacle, then they can choose to implement a mail-back program.

Dr. Wong stated that he would support the board making take-back programs voluntary.

Dr. Castellblanch motioned to make take-back programs voluntary unless required by local or federal law. There was no second to the motion.

Ms. Veale motioned for the board to move forward with the language as provided in the board meeting materials (the language has been provided following these minutes). Mr. Law seconded the motion.

President Gutierrez asked if Ms. Veale would amend her motion to include the requirement for the receptacle to be physically blocked when the pharmacy is closed. Ms. Veale and Mr. Law agreed to amend the language as follows.

1776.3 (a) Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for

destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner. In hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit slot on the collection receptacle and physically block patients from access to the collection receptacle by some means.

Dr. Castellblanch stated that he would be voting against the motion as it was clear to him that it was the intent of the board to make take-back programs voluntary.

President Gutierrez opened the floor for public comment.

A representative from Sacramento County asked the board not to preempt county ordinances.

Megan Harwood representing the Orange County Prescription Drug Abuse Coalition stated that their organization is concerned that there are not enough reverse distributors to handle the volume of the drugs being returned. Ms. Herold explained that the DEA requires the use of reverse distributors.

Ms. Harwood also expressed concern that if drug manufacturers are required to fund take-back programs they will raise the price of medication.

Ms. Sanborn, Executive Director of the California Product Stewardship Council, stated that many other countries have take-back programs that are funded by the drug manufacturers. She explained that in an Alameda county court case there were stipulated facts that showed that the cost of a take-back program would be one-cent per every ten dollars spent. Ms. Sanborn stated that in Alameda county one billion dollars' worth of drugs were sold; the cost for drug manufacturers to fund a take-back program would have only been one million dollars.

A representative from Santa Rosa asked the board not to remove the option for counties to mandate take-back programs. He also expressed concern with the requirement to physically block the receptacle.

A representative from San Francisco explained that the county of San Francisco currently has twelve pharmacies participating in their pilot take-back program. She stated that the San Francisco program will be funded by drug manufactures and will require five take-back locations for every supervisorial district (55 total pharmacies). She concluded that San Francisco does not anticipate the need to mandate the program; however, they would like the option to mandate participation if they cannot meet the required number of participants.

The California Retailers Association, the National Association of Chain Drug Stores, and CPhA offered their support of the board's motion, including making the programs voluntary.

A representative from Walgreens thanked the board for their in-depth discussion and offered support of the board’s motion.

Lauren Burton with CVS Health stated their support of the board’s motion. Ms. Burton explained that in counties with mandated programs, CVS complies by utilizing mail-back envelopes.

Don Gilbert representing Rite Aid stated their support of the board’s motion.

President Gutierrez called for the vote on Ms. Veale’s prior motion.

Motion: Move forward in the regulation process with the language provided in the board meeting materials with the amendment to 1776.3 (a) as provided below.

1776.3 (a) Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner. In hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit slot on the collection receptacle and physically block patients from access to the collection receptacle by some means.

M/S: Veale/Law

Support: 7 Oppose: 1 Abstain: 1

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch		x		
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez	x			
Schaad			x	
Veale	x			
Weisser	x			
Wong	x			

Dr. Castellblanch stated that he is very concerned with the opioid epidemic and the rise in overdose deaths. He added that in his opinion, the board is making it harder for patients to dispose of unwanted opioids.

c. Board Approved – Submitted for Administrative Review by the Department of Consumer Affairs or the Office of Administrative Law

1. Proposed Regulations to Add Title 16 CCR section 1746.2 related to Nicotine Replacement Products

Chairperson Lippe reported that at the January 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to add text to 16 California Code of Regulations section 1746.5 for Nicotine Replacement Products. The 45 day comment period began on May 8, 2015 and ended on June 22, 2015. He added that board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process at the end of July 2015.

Chairperson Lippe reported that on December 15, 2015, the file was submitted for final review by the Office of Administrative Law for final approval, pursuant to the Administrative Procedures Act. The estimated date of completion is January 29, 2016. He noted that board staff has requested an immediate effective date upon completion of the review.

There were no comments from the board or from the public.

2. Proposed Regulations to Add Title 16 CCR section 1746.3 related to Naloxone Hydrochloride (Non-Emergency)

Chairperson Lippe stated that at the April 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to amend the emergency regulation text of 16 California Code of Regulations Section 1746.3. The 45 day comment period began on May 22, 2015 and ended on July 13, 2015.

Chairperson Lippe explained that a 15 day comment period was required due to an error made with the incorrect proposed text being noticed in May 2015. The 15-day comment period began on September 4, 2015 and ended September 19, 2015.

Chairperson Lippe reported that the Board approved the final language at the September 2015 Board Meeting. Board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process on the October 16, 2015. As of December 15, 2015, the file is being reviewed by the Office of Administrative Law for final approval, pursuant to the Administrative Procedures Act.

Chairperson Lippe stated that the estimated date of completion is January 29, 2016. He noted that board staff has requested an immediate effective date upon completion of the review.

There were no comments from the board or from the public.

President Gutierrez asked if there were any further comments from the board. Dr. Castellblanch asked that the board agendaize a review of the disciplinary process, specifically the fact patterns the board considers when determining the severity of the disciplinary action it will take against a licensee.

President Gutierrez adjourned the meeting at 5:10 p.m.



January 14, 2016

Department of Health
California Board of Pharmacy
1625 North Market Blvd
Suite N219
Sacramento, CA 95834

Hand Delivered by Navid Vahedi B.Sc Pharm.D

Re: Proposed Changes to Section 1751.7 (e) (1)

Dear Board Members,

On September 22, 2014, bioMérieux was granted a face-to-face meeting with the FDA to present our Rapid Microbiological Method for sterility testing, ScanRDI®. During this meeting, we also presented our proposal for validation and implementation of the ScanRDI in 503B Drug Compounding Outsourcing facilities. This presentation was well-attended by sixty (60) FDA representatives from various offices of the Center for Drug Evaluation and Research (CDER). Subsequently, we have also delivered this information to the local branches of the FDA responsible for inspection of 503B facilities in the state of California at their request.

Compounding Pharmacists face many challenges related to sterility testing of their compounds—especially when the products have short shelf lives because the 14-day incubation period mandated by USP <71> is not manageable. Despite this limitation, USP allows for use of alternative microbiological methods as described in the USP general notes and Chapter <1223>.

Specifically, USP <797> allows an alternative method if verification results demonstrate that the alternative is at least as effective and reliable as the USP Membrane Filtration method..

To demonstrate the ScanRDI method's equivalency to USP <71>, we have generated extensive Performance Qualification data proving that the ScanRDI was not only equivalent to the traditional method but is actually 66% more effective at detecting microorganisms than growth-based methods. Consequently, we have submitted these data and validation strategy as an amendment to our type V Drug Master File (DMF) #14621 with the FDA..

ScanRDI has been used to release sterile drug products by traditional "Big Pharma" companies for over 20 years and is present in many governmental agencies including the FDA, CDC and NASA.. Many Sterile Drug Compounders are following their lead because the rapid results give them confidence they are releasing a product that is free of microbial contamination.

Because of this, we respectfully request that you consider amending in your section, subdivision 1751.7 (e) (1) with the following change.

"An alternate sterility test method to USP 71 may be used if verification results demonstrate that the alternative is at least as effective and reliable as the USP Membrane Filtration method or the USP Direct Inoculation of the culture Medium method where the Membrane Filtration method is not feasible."



We realize you may have some questions and welcome the opportunity present you the same information given to the FDA because we feel the ScanRDI can benefit many pharmacists in the state of California and help secure the safety of Compounded Sterile Products in your state.

To do this, we respectfully request a one-hour appointment with you during your next board meeting

Please let us know how to best arrange this presentation by contacting me directly by email or by phone.

Best Regards

A handwritten signature in black ink that reads "Ph. Gadai". The signature is stylized and fluid.

Philippe Gadai Pharm. D Ph.D
US Deputy Industry Director
Philippe.gadai@biomerieux.com
Ph: (609) 575 1880



Navid Vahedi <nvahedi@gmail.com>

Navid to BOP

2 messages

Herb L. Weinberg <hweinberg@fentonlawgroup.com>

Thu, Jan 14, 2016 at 6:01 AM

To: Navid Vahedi <nvahedi@gmail.com>

From Navid to Virginia Herold, Executive Officer, California State Board of Pharmacy:

Dear Ms. Herold:

It is my understanding that the Board of Pharmacy is considering adopting USP 71 as the sole accepted standard for determining sterility of products prepared by sterile compounding pharmacies. If such is the case, the board will be at odds with the standards presently recommended by the FDA.

USP 71 requires a quarantine period of 14 days before a product may be dispensed. Such a lengthy quarantine is certain not to be in the best interest of a patient who requires prompt access to medication prescribed by his or her physician. In such an event, the pharmacy could not compound a batch, which would require a quarantine period, but would be limited to preparing a single sterile product which, as you are aware, may be dispensed without testing. On the other hand, sterility of a compounded product may be confirmed in just a matter of hours, by use of a Rapid Scan RDI microbial detection test.

In fact, adoption of USP 71 by the board, as the sole means of determining the sterility of a product, is likely to lead to pharmacists abandoning batch production, in favor of compounding single units, untested for sterility.

I believe that the best interests of the patient and the pharmacy would be served by adhering to present FDA guidelines, which would permit the patient quicker access to medication, at less expense.

Your consideration is respectfully requested.

Herb L. Weinberg

FENTON LAW GROUP, LLP

1990 S Bundy Drive Suite 777

Los Angeles, CA 90025

T 310-444-5244

Direct 310-444-5246

F 310-444-5280

hweinberg@fentonlawgroup.com

THIS EMAIL IS INTENDED FOR THE USE OF THE ADDRESSEE(S) NAMED ABOVE ONLY AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED AND CONFIDENTIAL. IF YOU ARE NOT AN INTENDED RECIPIENT, PLEASE DELETE THIS EMAIL AND DO NOT DISSEMINATE, DISTRIBUTE, OR COPY IT.

Navid Vahedi <nvahedi@gmail.com>
To: "Herb L. Weinberg" <hweinberg@fentonlawgroup.com>

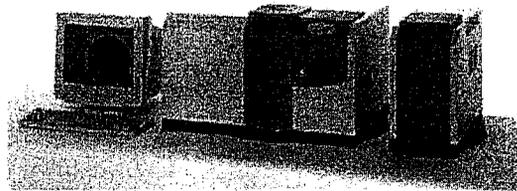
Thu, Jan 14, 2016 at 7:45 AM

Can you tell me where in the law book it states that 1 Rx is exempt from testing just so I know where to refer them to.

Navid

[Quoted text hidden]

Acceptance by the FDA of a Type V Drug Master File for the ChemScanRDI analyser



Within the program aiming for the FDA acceptance of ChemScanRDI for in-process and product control, CHEMUNEX have completed a Drug Master File (DMF) for the Federal Drug Agency.

The FDA have confirmed the receipt of the Type V DMF and have attributed the number DMF 14621. The ChemScanRDI users can henceforth refer to this document number with their validation submission file.

The first part of the DMF contains the data to support the CHEMUNEX system technology, that is instrumentation, software and reagents, for the rapid detection and enumeration of bacteria, spores, yeast and moulds.

The second part concerns the validation of the base technology and incorporates data to support the applications for process water microbial analysis. This section includes and completes the data already published in *Pharmacopeial Forum* (Volume 25 – Number 1 - Jan-Feb, 1999 – p. 7626-7645).

The details of the DMF are:

- Drug Master File #: DMF 14621
- Type V submission
- Title: Description of the data to support use of solid phase cytometer (ChemScanRDI) for the measurement of viable micro-organisms in pharmaceutical water systems.

Benefits of ScanRDI® Over USP<71> for Sterility Testing

Dr. H. Eric Feinstein, Ph.D.
Dr. Navid Vahedi, R.Ph., Pharm. D.,

Fusion Rx Compounding Pharmacy/
Fusion IV Home Infusion
Los Angeles, CA

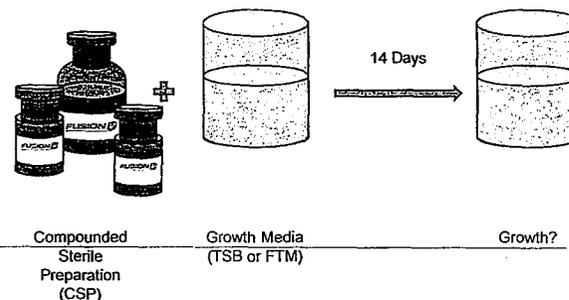
January 19th, 2016



Thank you for having us come and speak with you today.

We would like to discuss the status quo regarding sterility testing for compounded sterile products vs. a stricter, more dependable method known as ScanRDI®, and why the board should permit its use.

USP<71>: The “Gold Standard”

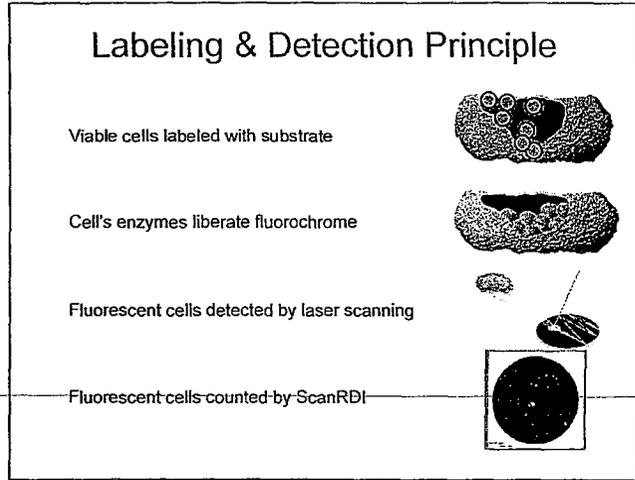
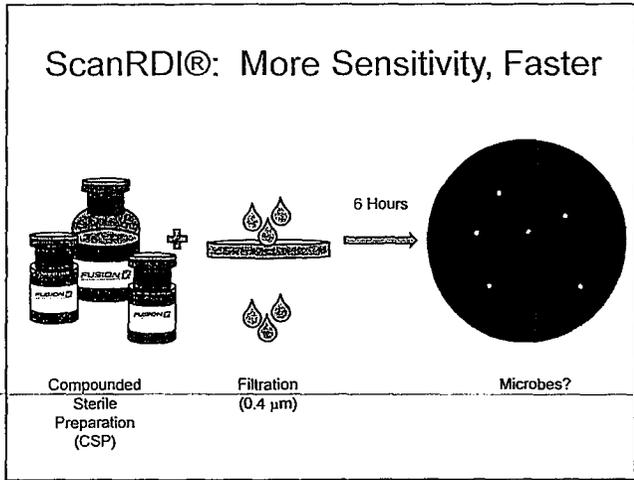


Currently, USP<71> outlines a method for testing for sterility in compounded sterile preparations (CSPs).

#First, a predetermined amount of CSP is removed from the final product, known as “the sample”.

#Next, the sample is then introduced to microorganism growth media (either Trypticase Soy Casein Digest Broth (TSB) or Fluid Thioglycollate Medium (FTM)).

#This mixture is allowed to incubate for fourteen days to promote growth of any microorganisms which may be present. At the end of the fourteen days, the sample is examined to see if there is growth (a positive result) or not (a negative result).



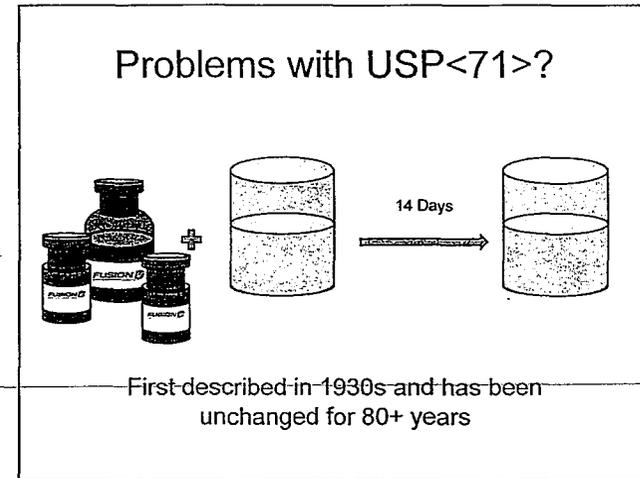
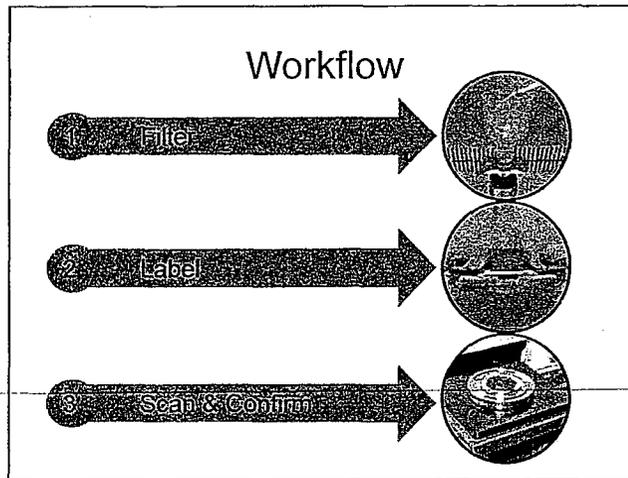
Using the ScanRDI®, we can get a result with higher confidence, much faster.

#We start with the same amount of CSP as described in USP <71>.

#From there, the sample is filtered through a 0.4 micron filter. This step is effective in capturing 100% of microorganisms in the sample because the pores in the membrane are smaller than a microorganism.

Next, the filter is treated with proprietary background and viability stains to improve the detection of microorganisms.

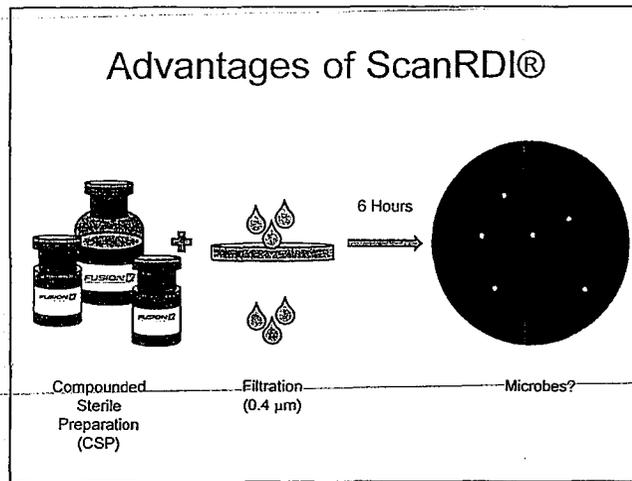
#The filter is then aseptically transferred to the ScanRDI® machine, where lasers scan the filter for the presence of microorganisms in a process called "Laser Scanning Cytometry," or "LSC". #Only living microbes are able to fluoresce and be detected.



There are several problems with the current USP<71> method as it is a relic from many decades ago which has been subject to much criticism over the last 50+ years.

The main criticisms with the method are:

1. The two choices for growth media, TSB and FTM, cannot be guaranteed to foster the growth of all microorganisms which could be harmful to humans. Additionally, it should be noted that some microbes prefer solid media as opposed to liquid media. The choices in the current procedure simply reflect those media to which all parties in the decision making process could agree.
2. 14 days is not only a long time to wait for a test result, but more importantly, it may not be long enough to ensure enough growth of any microorganisms. In fact, a growing body of evidence suggests that there are a large number of microorganisms that are unable to replicate under standard laboratory conditions (they are called "Viable But Not Culturable," or "VBNC").



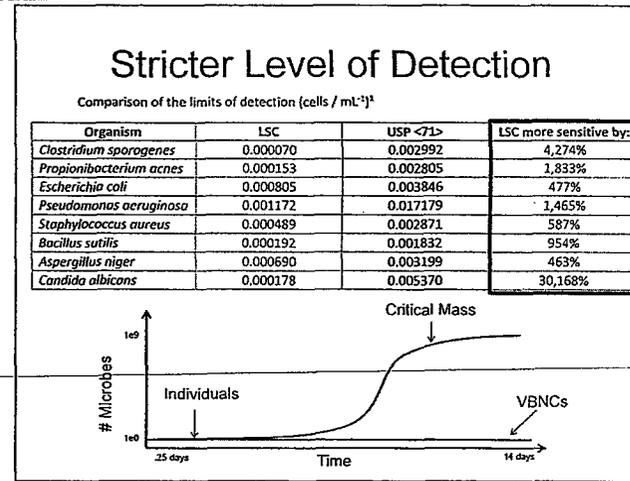
What would be best would be to have a test that did not require the growth of microbes, while being more sensitive, addressing both the concerns of USP<71>'s critics.

In fact, we do have such a test in ScanRDI®.

Without the need to sit and wait while microbes grow, the test can happen in under a working day, allowing patients to receive their medicine much faster.

Additionally, because no growth is required for ScanRDI®, *any* contaminating microbe can be detected, not just those for which that the assay is particularly suited.

Most crucially, the ScanRDI® provides a much higher level of detection than the standard USP<71> test because it can find individual microbes.



How much *better* is better?

Here we see a quantitative comparison of several different bacteria, yeast, and fungi.

The column marked "LSC" shows the limit of detection of the number of cells per mL of fluid using ScanRDI®, while the column marked "USP<71>" shows the limit of detection of the number of cells per mL of fluid using the standard 14 day test. #ScanRDI® delivers many times more detecting power than the standard USP <71> test.

#This advantage is provided by ScanRDI® being able to detect individual microbes, without the need for them to reach a critical mass to be detected. Its laser-based vision system is far superior to our own eye, providing a much stricter detection methodology.

As such, the ScanRDI® method is appropriate for use as a rapid alternative to the growth-based sterility test method.

Statistically Strict

Limit of Detection (LOD)	Detection rate of the ScanRDI system method is as good or better as the USP <71> sterility test method on the 6 USP microorganisms
Specificity	Ability of the ScanRDI method to detect the strains we use as control microbes
Robustness	Small variations within ScanRDI method will not impact results
Ruggedness	Different instruments, operators, reagents lots changes will not impact results

Current Examples

- FDA
 - Type V Drug Master File (#14621),
“Description of the data to support use of solid phase cytometer (Chem ScanRDI®) for the measurement of viable micro-organisms in pharmaceutical water systems.”
- Alcon
- GlaxoSmithKline

The test has already been deployed in the field and is approved for use by various entities.

The FDA granted the manufacturer of the ScanRDI®, bioMérieux, the opportunity to present the technology at the FDA Facility in Silver Spring, Maryland in September 2014.

Now, the FDA—the strictest authority in the country—is *encouraging* drug manufacturers to identify more rapid sterility tests for their products as these items have very short shelf lives, and ScanRDI® is one of the options (according to 2CFR612).

Additionally, many pharmaceutical manufacturers are utilizing the ScanRDI® in their operations to perform sterility tests for their final products.

Superiority of ScanRDI®

"The limiting aspects of growth-based methods as an alternative for the sterility test can be avoided by use of a *Rapid Microbiological Method (RMM)* technique that *does not require growth*. The use of a method that avoids growth requirements offers an additional advantage in that the *question of VBNC organisms is completely side-stepped*."



Scott Sutton, 2011

Here is a quote from Dr. Scott Sutton, who has 30 years of experience in the GMP pharmaceutical, medical device, cosmetics and personal products industries with extensive publications and presentations.

Conclusions

"An alternate sterility test method to USP<71> may be used if verification results demonstrate the alternative is at least as effective and reliable as the USP<71> Sterility Test Method."



In conclusion, the differences between USP <71> testing and utilizing ScanRDI® are stark: ScanRDI® is quicker, superior in accuracy and orders of magnitude more sensitive than USP <71>, all of which lead to higher confidence that a compounded sterile preparation is indeed sterile and thus provides a greater benefit to patient safety.

Therefore, we implore the California Board of Pharmacy to allow the use of ScanRDI® or any other technology yet to be developed in the future by adding in the follow #verbiage into the Sterile Compounding Rules for California:

References

1. Smith R, Von Tress M, and Tubb C. "Evaluation of the ScanRDI® as a Rapid Alternative to the Pharmacopeial Sterility Test Method: Comparison of the Limits of Detection," PDA Journal of Pharmaceutical Science and Technology, Vol. 64, Pgs. 356-363.
2. Moldenhauer J and Sutton SVW. "Towards an Improved Sterility Test," PDA Journal of Pharmaceutical Science and Technology, Vol. 58, No.6, Nov.-Dec. 2004. Pgs 284-286.
3. Sutton S. 2011. "Sterility Tests," in Rapid Sterility Testing, J. Moldenhauer (ed). PDA/DHI Publications. Pgs 7-24.
4. Jones DL, et al. "Solid-Phase, Laser-Scanning Cytometry: A New Two-Hour Method for the Enumeration of Microorganisms in Pharmaceutical Water," Pharmacopeial Forum, Vol 25:1. Pgs. 7626-7645.
5. Costanzo SP, et al. "Validation of the ScanRDI® for Routine Microbiological Analysis of Process Water," PDA Journal of Pharmaceutical Science and Technology, Vol. 56:4, Jul.-Aug. 2002.
6. Ramond B, et al. "Enumeration of Total Viable Microorganisms in an Antibiotic Raw Material Using ChemScan Solid Phase Cytometer," PDA Journal of Pharmaceutical Science and Technology, Vol. 54:4, Jul.-Aug. 2000.
7. Haghdooren E. "Development and Validation approach for a Rapid Sterility Test in a Contract Laboratory to Serve the Pharmaceutical Industry," Toxikon Europe, Berlin 27-02-2012.

Sterility Testing Information

FDA Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice. September 2004

XI. STERILITY TESTING

B. Sampling and Incubation

Sterility tests are limited in their ability to detect contamination because of the small sample size typically used. For example, as described by USP, statistical evaluations indicate that the sterility test sampling plan "only enables the detection of contamination in a lot in which 10% of the units are contaminated about nine times out of ten in making the test" (Ref. 13). To further illustrate, if a 10,000-unit lot with a 0.1 percent contamination level was sterility tested using 20 units, there is a 98 percent chance that the batch would pass the test.

Because of the limited sensitivity of the test, any positive result is considered a serious CGMP issue that should be thoroughly investigated.

USP38 General Notices:

6. TESTING PRACTICES AND PROCEDURES

6.30. Alternative and Harmonized Methods and Procedures

Alternative methods and/or procedures may be used if they provide advantages in terms of accuracy, sensitivity, precision, selectivity, or adaptability to automation or computerized data reduction, or in other special circumstances. Such alternative procedures and methods shall be validated as described in the general chapter *Validation of Compendial Procedures* < 1225 > and must be shown to give equivalent or better results. Only those results obtained by the methods and procedures given in the compendium are conclusive.

Note: USP38 <1223> VALIDATION OF ALTERNATIVE MICROBIOLOGICAL METHODS used in addition to <1225> for microbiological methods.

USP38 <797> PHARMACEUTICAL COMPOUNDING—STERILE PREPARATIONS

Sterility Testing

All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test (see *Sterility Tests* §711) before they are dispensed or administered. The *Membrane Filtration* method is the method of choice where feasible (e.g., components are compatible with the membrane). A method not described in the *USP* may be used if verification results demonstrate that the alternative is at least as effective and reliable as the *USP Membrane Filtration*.

Medication Article 9.1
Prescription Drug Take-Back Programs
As Discussed at the January 19, 2016 Board Meeting

Section 1776

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board and licensed skilled nursing facilities may offer, under the requirements in this article, specified prescription drug-take back services to the public to provide options for the public to destroy unwanted, unused or outdated prescription drugs. Each of these entities must comply with regulations of the federal Drug Enforcement Administration and the Board of Pharmacy regulations contained in this article.

All board-licensed authorized collectors should be vigilant to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods. Federal, state and other laws prohibit the deposit in drug take-back receptacles of the following: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, hazardous medications (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers).

Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs authorized under this article.

Section 1776.1 Pharmacies

- (a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.
- (b) Pharmacies may provide take-back services to patients as provided in sections 1776 - 1776.6. Retail pharmacies and hospital/clinics with onsite pharmacies may establish collection receptacles in their facilities. Pharmacies may operate collection receptacles as specified in in section 1776.4 in skilled nursing facilities licensed under California Health and Safety Code section 1250(c).
- (c) There are multiple federal and state requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.
- (d) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, including controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a patient, they are not to be separated by pharmacy staff or others.

- (e) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage shall be placed on collection receptacles as referenced in section 1776.3.
- (f) Prescription drugs that are eligible for collection in drug take-back programs operated by pharmacies are only those prescription drugs that have been dispensed by a pharmacy or practitioner to a patient or patient's agent. Dangerous drugs that have not been dispensed to patients (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in pharmacy drug take-back programs.
 - (1) Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public.
 - (2) A pharmacy shall not accept or possess prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.
 - (3) A pharmacy shall not dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock in a drug take-back collection receptacle. Instead the pharmacy must return these items to a reverse distributor.
- (g) A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back program. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied, surrendered or revoked.
- (h) Any pharmacy that operates a drug take-back collection program as authorized in this article shall notify the board on a form designated by the board within 30 days of establishing the collection program. Additionally:
 - (1) Any pharmacy that ceases to operate a drug take-back program shall notify the board within 30 days on a form designated by the board. If the pharmacy later ceased to operate the collection receptacle, the pharmacy must notify the board within 30 days.
 - (2) Any pharmacy operating a mail back program or maintaining collection receptacles shall identify to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.
 - (3) Any tampering with a storage receptacle or theft of deposited drugs shall be reported to the board with 14 days.
 - (4) Any tampering, damage or theft of a removed liner shall be reported to the board within 14 days.
- (i) If a pharmacy later ceases to operate a collection receptacle, the pharmacy must notify the Drug Enforcement Administration within 30 days.

1776.2 Mail Back Package and Envelope Services from Pharmacies

- (a) Pharmacies that provide prescription drug take-back services may do so by

establishing mail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location.

- (b) All envelopes and packages must be preaddressed to a location registered with the Drug Enforcement Administration as a collector that has onsite a method appropriate to destroy the prescription drugs. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed to be delivered to facilities that comply with this section.
- (c) The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.
- (d) The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and certain instructions for users to mail back drugs.
- (e) The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6.
- (f) Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.
- (g) Once filled with unwanted prescription drugs, the mail back packages or envelopes shall be mailed and not accepted by the pharmacy for return, processing or holding.

1776.3 Collection Receptacles in Pharmacies

- (a) Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.
- (b) The pharmacy operating the collection receptacle must securely install the receptacle so it cannot be removed. The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas.
- (c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care. When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle.
- (d) The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner.
- (e) The pharmacy is responsible for the management and maintenance of the receptacle. Pharmacy staff shall not accept, count, sort or handle prescription drugs returned from the public, but instead direct the public to deposit the drugs into the collection receptacle themselves.
- (f) A liner as used in this article shall be made of material that is certified by the

manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.

- (1) The liner shall be waterproof, tamper evident and tear resistant.
 - (2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor.
- (g) The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed or counted.
- (h) If the liner is not already itself rigid or already inside of a rigid container as it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Rigid containers may be of any color. All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The containers shall be capable of being sealed and be kept clean and in good repair.
- (i) The liner may be removed from a locked receptacle only by two employees of the pharmacy who shall immediately seal the liner and record in a log their participation in the removal of each liner from a collection receptacle. If the liner is not already contained in a rigid container within the receptacle, the two employees shall immediately place the liner in a rigid container. Liners and their rigid containers shall not be opened, x-rayed, analyzed or penetrated.
- (l) Liners and their rigid containers that have been filled and removed from a collection receptacle, must be stored in a secured, locked location in the pharmacy no longer than three days.
- (m) The pharmacy shall maintain a log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:
- (1) The unique identification numbers of all unused liners in possession of the pharmacy,
 - (2) The unique identification number and dates a liner is placed in the collection receptacle,
 - (3) The date the liner is removed from the collection receptacle,
 - (4) The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and
 - (5) The date the liner was provided to a licensed DEA-registered reverse distributor for

destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor. If a common carrier is used to transport the liner to the reverse distributor, the company used, the signature of the driver, and any related paperwork (invoice, bill of lading) must be recorded.

- (n) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by licensed reverse distributor pick-up at the licensed pharmacy's premises.
- (o) The collection receptacle shall contain signage developed by the board advising the public that it is permissible to deposit Schedule II-V drugs into the receptacle, but not Schedule I drugs. Labeling shall also identify that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.
- (p) The board shall develop signage to appear on the collection receptacle to provide consumer information about the collection process.

1776.4 Collection in Skilled Nursing Facilities

Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate in drug take-back programs as authorized by this article.

- (a) Skilled nursing facility personnel may dispose of a current resident's unwanted or unused prescription drugs by using mail back packages or envelopes and packages based upon a request by the resident patient. Mail back envelopes and packages shall conform to the requirements specified in section 1776.2. Records shall be kept by the skilled nursing facility noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.
- (b) Only retail pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs.
 - (1) Any pharmacy and hospital/clinic with an onsite pharmacy operating collection receptacles in skilled nursing facilities shall be registered and maintain registration with the DEA as collectors.
 - (2) Any pharmacy or hospital/clinic with an onsite pharmacy that operates a collection receptacle at a skilled nursing facility shall notify the board within 30 days of establishing a collection receptacle on a form designated by the board.
 - (3) Any pharmacy or hospital/clinic with an onsite pharmacy that ceases to operate a collection site at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.
 - (4) Any pharmacy operating a collection site at a skilled nursing facility shall list all collection receptacles it operates annually at the time of renewal of the pharmacy

license.

- (c) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.
- (d) Every pharmacy and hospital/clinic pharmacy that operates a collection site at any skilled nursing facility shall notify the board within 14 days of any loss from the collection receptacle or secured storage location for the storage of removed liners.
- (e) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.
- (f) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.
- (g) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be removed. The collection receptacle shall have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner.
- (h) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.
 - (1) The liner shall comply with provisions in this article. The receptacle shall allow deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be viewed, removed or counted.
 - (2) If the liner is not already itself rigid or already inside of a rigid container as it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Rigid containers may be of any color. All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The rigid containers shall be capable of being sealed and be kept clean and in good repair.
- (i) A liner as used in this article shall be made of material that is certified by the manufacturer to meet American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.
 - (1) The liner shall waterproof, tamper evident and tear resistant.
 - (2) The liner shall be opaque to prevent viewing or removal of any contents once the

liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer.

- (j) The collection receptacle shall prominently display a sign indicating that prescription drugs and controlled drugs in Schedules II – V may be deposited. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.
- (k) Once deposited, the prescription drugs shall not be counted, inventoried or otherwise individually handled.
- (l) The installation, removal, transfer and storage of inner liners shall be performed only by:
 - (1) One employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or
 - (2) By or under the supervision of two employees of the authorized collector pharmacy.
- (m) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.
- (n) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.
- (o) Records of the pickup, delivery and destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transported each liner.

1776.5 Reverse Distributors

- (a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered DEA as a collector may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.
- (b) A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated by an appropriately licensed DEA distributor.

- (c) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.
- (d) A reverse distributor shall not employ as an agent or employee anyone who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.
- (e) Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.
- (f) For each sealed liner or mail back package received from collectors or law enforcement pursuant to federal CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes/package, including the:
 - 1. Date of acquisition
 - 2. Number and the size (e.g., five 10-gallon liners, etc.)
 - 3. Inventory number of each liner or envelope/package
 - 4. The method of delivery to the reverse distributor, the signature of the individuals delivering the liners to the reverse distributor, and the reverse distributor's employees who received the sealed liner
 - 5. The date, place and method of destruction
 - 6. Number of packages and inner liners received
 - 7. Number of packages and inner liners destroyed
 - 8. The number and signature of the two employees of the registrant that witnessed the destruction.

1776.6 Record Keeping Requirements for Board Licensees Providing Drug Take-Back Services

Each entity authorized by this article to collect unwanted prescription drugs from patients shall maintain the following records.

- (a) When obtaining unused mail-back packages and envelopes for future distribution:
 - 1. The collector pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy, the number of packages/envelopes made available to the public, and the unique identification number of each package.
 - 2. For unused packages and envelopes provided to a skilled nursing facility or third party to make available to patients and other authorized individuals: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification number.
- (b) For each mail-back package or envelope distributed by a pharmacy, the pharmacy shall record the serial number of each package or envelope distributed and the date distributed.
- (c) For sealed mail-back packages received by the reverse distributor: the date of receipt

- and the unique identification of the individual package or envelope,
- (d) For sealed mail back packages destroyed onsite by the reverse distributor collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.
 - (e) For pharmacies using collection receptacles, for each liner:
 - 1. Date each unused liner is acquired, its unique identification number and size (e.g., five gallon, 10-gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.
 - 2. Date each liner is installed in a receptacle, the address of the location where each liner is installed, the unique identification and size (e.g., five gallon, 10-gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.
 - 3. Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each removal.
 - 4. Date each sealed inner liner is transferred to storage, the unique identification and size (e.g., 5-gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.
 - 5. Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it and the signature of the driver.
 - (f) For each reverse distributor (wholesaler or third-party logistics provider) accepting liners, immediately upon receipt of a liner:
 - 1. The date of receipt of each liner, the unique serial number of the liner, the pharmacy from which the liner was received, the method by which the liner was delivered to the reverse distributor (e.g., personal delivery by two pharmacy staff, shipping via common carrier).
 - 2. For each liner destroyed by the reverse distributor collector: the method and date of destruction, listed by the unique identification number of liner and other items required by (f)(1), and the names and signatures of the two employees of the registrant who witness the destruction.

Dear Members and Staff of the Board of Pharmacy,

Below are comments on the proposed Section 1776.1, regulating takeback programs in pharmacies.

I think the current proposal shows progress, but there are still a number of areas of concern. See comments in bold below.

Section 1776.1 Pharmacies

- (a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.

This could potentially lead to conflict where local or other laws mandate participation. I suggest adding language such as “Provision of such services is voluntary unless required by local, state or federal law.”

(e) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy’s collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage shall be placed on collection receptacles as referenced in section 1776.3.

Many pharmacies also host sharps receptacles. I would suggest “The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy’s drug collection receptacles.”

f(2) A pharmacy shall not accept or possess prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.

This makes no sense to me. Why leave them no viable way to dispose of medications?

(m) The pharmacy shall maintain a log to record information about all liners that have been placed into or removed from a collection receptacle.

The record-keeping requirements for pharmacies are burdensome and unnecessary. Collectors can provide all of this information.

1776.4 Collection in Skilled Nursing Facilities

Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate in drug take-back programs as authorized by this article.

(a) Skilled nursing facility personnel may dispose of a current resident’s unwanted or unused prescription drugs by using mail back packages or envelopes and packages based upon a request by the resident patient. Mail back envelopes and packages shall conform to the requirements specified in section 1776.2. Records shall be kept by the skilled nursing facility noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.

(b) Only retail pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs.

This seems unnecessary, burdensome and likely beyond the Board's authority. What pharmacy will take responsibility for collection at a skilled nursing facility they have nothing to do with? This will just leave them with no viable disposal options.

Thank you,

Tim Goncharoff
County of Santa Cruz

Comments on Advanced Practice Pharmacist 1730.1
Board of Pharmacy Meeting, January 19, 2016
Douglas Barcon, Pharm.D.

Members of the Board,

I am Douglas Barcon, a pharmacist and member of the CSHP Council on Professional Affairs. My comments today are made as an individual and not as a member of CSHP or the Council on Professional Affairs. I have made previous comments to the Board of Pharmacy in writing and at two Board of Pharmacy meetings in Irvine regarding the three criteria for qualification for Advanced Practice Pharmacist. I also contacted the West Covina and Sacramento offices of Senator Ed Hernandez on this matter after the last board of pharmacy meeting I attended.

My concerns are patient safety and the wide variation of advanced practice pharmacists the statute has created and the problems the proposed regulations would create. Board of Pharmacy regulation 1730.1 and SB-493 in section 4210(a)(2) both specify that an applicant for advanced practice pharmacist must meet two of three requirements, which include, a certification in a relevant area of practice, a postgraduate residency of which 50 percent is direct patient care services, and provision of clinical services under a collaborative practice agreement or protocol for at least a year. The way the statute is written, it favors a residency over experience, and the lowest common denominator becomes the residency and the minimum of six-months collaborative practice experience it includes regardless of how many years passed since it was completed. How fair is this for pharmacists without residencies?

During Board of Pharmacy board meetings and committee meetings, the board then proposed to limit the experiential criteria to within 10 years of the date of application for advanced practice pharmacist of which 1500 hours must be within one year, but there is no time limitation placed upon a residency. This means that a residency is a qualifier for the entire career of the pharmacist and that all a pharmacist with a residency would require is the minimum one-year of qualifying experience regardless of how many years passed since the residency was obtained. It would be necessary for a pharmacist without a residency to obtain a qualifying certification regardless of how much experience he or she has completed, even if it was within four years of application, which would be exclusionary and discriminatory. Consequently, a pharmacist without a residency may decide against becoming an advanced practice pharmacist, while the pharmacist with a residency and no certification can just skate through. Moreover, a pharmacist without a residency who seeks to become an advanced practice pharmacist would likely have a better skill level, competence, and knowledge base than a pharmacist with only a residency and experience because he or she would have to complete and maintain a certification relevant to their practice. Under the current statute, a new grad pharmacist with a residency and one-year of experience (no reference as to whether this is concurrent with the residency or sequential) is set for life as an advanced practice pharmacist, but a pharmacist with only a Pharm.D. and several years of collaborative practice experience is not.

With that said, my first suggestion is to apply any time limitation equally to the experiential criteria and residency criteria, because six-months of collaborative practice in a residency that was obtained 20 or 30 years ago does not mean much compared to having current experience or

a certification that must be maintained. If the Board of Pharmacy proposes a 10-year limitation on experience, it should apply that limitation, or perhaps less than 10 years, to a residency. While grandfathering older pharmacists with many years of collaborative practice experience in acute care or ambulatory care would be prudent, SB-493 does not permit this, and as such would require a difficult statutory change to implement.

My alternative suggestion is to mandate that all advanced practice pharmacists maintain a certification relevant to their area of practice as one of the three criteria specified in 4210(a)(2). This change does not require a change of the statute and is no different in concept than the board placing a time limitation on experience. Yes, this may result in a decrease in the number of advanced practice pharmacists, but it would increase the level of quality and help ensure the competence of the advanced practice pharmacist. In this manner, there is equality placed on the pharmacist applicant for advanced practice pharmacist. When combined with or without any time limitations, it helps validate that a pharmacist without a residency or with a residency is qualified and competent for advanced practice pharmacist throughout the period of time the pharmacist maintains advanced practice pharmacist licensure.

I am hopeful that the Board of Pharmacy agrees with one of my suggestions or a combination of them.

Thank you,

A handwritten signature in cursive script that reads "Douglas Barcon".

Douglas Barcon, Pharm.D.
Barcon & Associates
P.O. Box 5646
Diamond Bar, CA 91765