COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

Pharmacy Advisory Committee
Meeting held via remote WebEx
Boston, Massachusetts, 02114
October 23, 2024

Advisory Committee Members Present

Edmund Taglieri, RPh, MSM, NHA (Chair Designee by James Lavery)
John P. Mistler, RPh, PharmD, MBA, BCSCP, CPH (Expert in cGMP)
Timothy D Fensky, RPh, DPh, FACA (Expert in USP <71>)
John Walczyk, RPh, PharmD (Expert in USP <795>)
Antoinette Lavino, RPh, BCOP (Expert in USP <797>)
Sylvia B. Bartel, RPh, MHP (Expert in USP <797>)
Francis McAteer (Expert in Microbiology)
David H. Farb, PhD (Expert in Clinical Pharmacology)
Michael J. Gonyeau, RPh, PharmD, MEd, BCPS, FNAP, FCCP (Expert in Clinical Pharmacology)

Board of Pharmacy Members Present

Sami Ahmed, RPh, PharmD, BCPS, BCSCP
Caryn Belisle, RPh, MBA

Advisory Committee Members Not Present

Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics)
Karen B. Byers, MS, RBP, CBSP (Expert in Microbiology)

Board Staff Present

Edmund Taglieri, RPh, MSM, NHA, Pharmacy Substance Use Disorder Program Supervisor
Monica Botto, Assistant Executive Director
Jacqueline Petrillo, RPh, PharmD, JD, General Counsel
William Frisch, RPh, Director of Pharmacy Compliance
Michelle Chan, RPh, Quality Assurance Pharmacist
Joanne Trifone, RPh, Director of Investigations
Christian Nelson, APPE Student, Northeastern University

TOPIC I. **Call to Order and Attendance** **Time: 10:05am**

Call to Order, by Edmund Taglieri at 10:05am and announces that the meeting is being recorded.

Roll call attendance: John Mistler, Timothy Fensky, John Walczyk, Antoinette Lavino, Sylvia Bartel, Francis McAteer, Michael Gonyeau

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TOPIC II. **Approval of Agenda** **Time: 10:07am**

Changes: No additional changes

Motion by T. Fensky and seconded by A. Lavino and voted unanimously by those present to approve the agenda with no changes.

Roll call vote: John Mistler, Timothy Fensky, John Walczyk, Antoinette Lavino, Sylvia Bartel, Francis McAteer, Michael Gonyeau, Edmund Taglieri

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TOPIC III. Approval of Board Minutes for 6/12/2024 meeting **Time: 10:08am**

Changes: No additional changes

Motion by T. Fensky and seconded by S. Bartel and voted unanimously by those present to approve the 6/12/24 meeting minutes with no changes.

Roll call vote: John Mistler, Timothy Fensky, John Walczyk, Antoinette Lavino, Sylvia Bartel, Francis McAteer, Michael Gonyeau, Edmund Taglieri

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TOPIC IV. Recommendation Document 24-02 "Rapid Sterility Testing"

Presented: Sami Ahmed, President Elect of MA Board of Pharmacy **Time: 10:09am**

Discussion: On behalf of the Board of Pharmacy members, input on the topic was requested.

TOPIC V. Provide expert input on the utilization of rapid sterility testing technologies by sterile compounding pharmacies to include validation of said testing technologies.

Time: 10:10am

Discussion:

W. Frisch – Initiated the discussion seeking expert input on the use of Rapid Sterility Testing (RST) in compounding pharmacies, especially with nonresident pharmacy licensing on the horizon. Proposed the need for a guidance document to promote public safety, noting that while USP <797> does not prohibit RST methods, it requires validation as per USP <1223>.

M. Chan – Presented key questions for the committee to consider, including when pharmacies should use RST, whether they should rely solely on RST for batch release, and the validation process for RST methods.

F. McAteer – Highlighted the evolving landscape of microbiology and the applicability of RSTs for short-shelf-life pharmaceutical products. Stressed that RSTs must undergo rigorous validation, including performance qualification comparing RST to traditional methods, and each formulation needing its own method suitability testing.

J. Walczyk and F. McAteer – Both noted that the responsibility for testing falls largely on labs if not performed in-house by pharmacies, which must ensure method suitability before results are provided. They discussed the importance of maintaining documentation and the necessity for pharmacies to ensure their contract labs are compliant.

Members discussed the already large and growing amount of RST technologies available for use, including the process by which microbiologists are involved to clarify potential contamination and the prevalence of false positives.

F. McAteer – Noted that if validation methodology is compliant with USP foundation documents, there is potential for RST to be used as a standalone approach for identifying microbial contamination.

Members inquired about the benefits of RSTs for shortened incubation times, reduced subjectivity in results analysis, and the implications for product beyond use dating. Members also acknowledged the potential shortcomings of RSTs, including difficulties associated with sample destruction and pitfalls of certain detection methods in identifying microbial contaminants.

Members discussed the context of using RSTs for both 503A and 503B pharmacies, acknowledging potential regulatory complexities and the need for thorough due diligence from licensees regarding lab validations and method suitability.

W. Frisch – Asked for final comments of PAC members.

F. McAteer – Informed the group of new regulatory information from USP regarding compendial methodologies for discussed testing methods that are currently being drafted.

E. Taglieri – Thanked the committee for their expert opinion and identified the meeting as a starting point for guidance document drafting.

TOPIC VI. Closing Remarks and Adjournment of Meeting **Time: 10:59am**

Comments: No additional comments

Adjournment:

Motion by T. Fensky and seconded by J. Walczyk and voted unanimously by those present to adjourn the meeting.

Roll call vote: Timothy Fensky, John Walczyk, Antoinette Lavino, Sylvia Bartel, Francis McAteer, Michael Gonyeau, Edmund Taglieri, David Farb

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