OSMA Fireside Chat
Meeting Date: November 18, 2024
Duration: 66 minutes

Speaker: Rear Admiral Raquel Peat, Assistant Surgeon General and Director of the Office of Orthopedic Devices

Key Takeaways

The fireside chat revealed several significant organizational developments and strategic initiatives within FDA. On the leadership and organizational front, RDML Peat acknowledged that while a new presidential administration may bring changes to CDRH, the organization will continue focusing on its core mission and vision of ensuring patients have access to safe and effective medical devices. A notable leadership change occurred with Jeff Shuren's retirement and Dr. Michelle Tarver's establishment as Center Director. The Office of Orthopedic Devices (OHT6) continues to demonstrate strong organizational health with over 105 staff members and one of the lowest attrition rates in CDRH. The office has expanded its capabilities in fiscal year 2024 with the addition of two new teams: one in Spinal Devices and another in Restorative Repair and Trauma Devices.

The organization's strategic direction is guided by three primary priorities extending through 2025: promoting a modern diverse workforce, enhancing organizational agility, and advancing health equity. Several key programs are evolving to support these priorities. The TPLC Advisory Program (TAP) will expand to include OHT6 starting in January 2025, marking a significant step in the office's evolution. The organization has also increased its focus on data integrity, particularly concerning testing companies in China and India where concerns have emerged. Additionally, a new initiative focusing on "home as healthcare hub" demonstrates the organization's commitment to expanding access to care beyond traditional settings.

Current programs are showing notable progress and developments. The Breakthrough Device Program has achieved significant milestones, with over 1,000 devices receiving designation and 124 advancing to marketing authorization. However, the organization is also addressing challenges in custom device submissions, which have seen a substantial increase to over 1,000 in 2023 across 14 companies. Compassionate use requests have also risen, with a particular concentration in joint arthroplasty cases. These developments are occurring alongside a new pre-market program redesign pilot that has been launched in the Spinal Devices group, indicating the organization's commitment to continuous improvement and adaptation to emerging needs in the medical device field.

Meeting Minutes

Opening Remarks
RDML Peat began by apologizing for missing the October 24th in-person OSMA meeting due to a family emergency. She explained that this fireside chat was arranged as an alternative to provide her planned presentation and answer questions. She acknowledged the recent election and noted that regardless of who would have been in power, a new administration means changes but emphasized that their central mission and vision will remain the same.

Leadership Introduction
RDML Peat introduced herself as the Assistant Surgeon General of the United States, a rank change effective May 1st, explaining that she works closely with the Surgeon General on public health initiatives across the span of the United States Public Health Service. She continues to serve as Director of the Office of Orthopedic Devices, which she noted has over 105 individuals and one of the lowest attrition rates within CDRH and Cedar Ridge.

CDRH Updates
RDML Peat discussed MDUFA V supported programs, noting they're already beginning to think about MDUFA VI. She outlined several program areas including the Total Product Life Cycle Advisory Program (TAP pilot), interactive reviews, and pre-submission review goals, which have been met. She reported the release of approximately 40 guidances related to digital transformation, an unprecedented number in such a short time span. The organization has focused on real-world evidence, digital transformation for internal documentation, the Digital Health Center of Excellence, Patient Science and Engagement, international harmonization, and the ASCA program for conformity assessment.

Performance Metrics
As of June 2023, RDML Peat reported that most MDUFA V review programs were either meeting their goals or on track to meet them. She described internal dashboards that help track progress toward particular goals, noting that when goals aren't being met, strategic conversations take place to address issues.

Patient Engagement and Innovation
The organization has issued draft guidance to clarify pre-submission usage and updated guidance on deficiency letters. They've expanded submission progress tracking systems and launched the TAP pilot, which has grown beyond its initial two Office of Health Technologies. Admiral Peat detailed a sustained increase in novel device authorizations, showing a fivefold increase since 2009, with a notable spike during the COVID pandemic period.

Breakthrough Device Program
The program has designated over 1,000 devices, with 124 receiving marketing authorization. RDML Peat noted a spike in 2021, particularly in orthopedics, which she

attributed to her increased communication about the program. She emphasized that the program enables interactive and timely communication, promotes pre- and post-market balance, facilitates flexible clinical study design discussion, and engages senior management.

OHT6 Updates
RDML Peat detailed the office's structure with three divisions: Joint Arthroplasty Division, Spinal Devices Division, and Restorative Repair and Trauma Devices Division. She announced the addition of two new teams in FY24, bringing the total to nine teams. The office conducts annual strategic planning meetings every February and has implemented various initiatives including post-market device safety communications.

Custom Devices and Compassionate Use
RDML Peat reported an increase in custom device activities, with orthopedics having the highest volume of reported custom devices annually. The numbers have grown from 575 in 2019 to over 1,000 in 2023, spanning 14 different companies. Similarly, compassionate use requests have increased, particularly in joint arthroplasty, with a 10-day review period for these submissions. FDA plans to address rising custom device submissions with target reduction to recommended 5 per year.

TAP Program Implementation
Looking ahead to 2025, RDML Peat explained that OHT6 will join the TAP program, which requires breakthrough designation for participation. She emphasized that companies must be early in their device development process and cannot have submitted pre-submissions after receiving breakthrough designation. The program operates on a first-come, first-served basis with a 30-day response time, and companies are limited to one device enrollment per fiscal year.

Closing Remarks
RDML Peat concluded by discussing the importance of interpersonal communication and team building, describing their annual week-long gathering at FDA White Oak. She emphasized their focus on continuous improvement, team management model, and creating an environment conducive to staff growth.

Question and Answer Session:

The first question addressed the status of the human tissue bone filler guidance, to which RDML Peat simply confirmed it was under clearance, though she couldn't provide additional details about where in the clearance process.

A discussion then emerged about the PPI (Patient Preference Information) guidance and its value across different submission types. RDML Peat emphasized that PPI is crucial for understanding patient preferences and encouraged companies to engage early through pre-submissions. She noted that for 510(k)s, which are "Me Too" products, the approach

depends on intended use. She stressed the importance of seeking early feedback and recommended that PPI reviews involve consultation with the Office of Strategic Partnerships and Technology Innovation (OST).

When asked about increased requests for clinical data in breakthrough submissions, RDML Peat clarified that clinical data isn't compulsory for breakthrough designation requests. She explained that companies can use literature and performance testing, noting that the main challenge is meeting "criteria one" threshold, which requires showing the product is better than what's currently on market. She offered to look into specific cases if companies contacted her directly.

Regarding the TAP (TPLC Advisory Program) program, RDML Peat explained that devices must be very early in development, have breakthrough designation, and cannot have done any pre-submissions or be already in clinical studies. She noted that the program allows for coordination with CMS for clinical study design.

Finally, when asked about potential policy shifts with the upcoming presidential administration change, RDML Peat reminded everyone that FDA has been around since 1906 and CDRH since 1976. She emphasized that they will continue focusing on their mission and vision while remaining agile, though she couldn't predict specific changes. Throughout the Q&A session, RDML Peat demonstrated a commitment to transparency and willingness to engage directly with industry members on their specific concerns.

Action Items

1. For Industry Members
    - Review updated pre-submission guidance document. https://www.fda.gov/media/177009/download
    - Submit comments on draft guidances before year-end deadlines.
    - Consider early engagement in TAP program if eligible (must have breakthrough designation and be early in development).

2. Future Engagement Opportunities
    - Participate in upcoming AAOS Town Hall on AI and orthopedic devices.
    - Engage in planned FY25 webinars and workshops
        - https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-events