FDA Holds Public Meeting on High-Dose Opioids – Hope for Intractable Pain Patients?

An eyewitness report from FIPR members Kristen Ogden and Anne Fuqua

The US Food and Drug Administration (FDA) held a public meeting on June 11-12, 2019, one of critical importance to many intractable pain patients. The meeting announcement stated: "FDA frequently hears from patients and healthcare providers that higher-dose opioid analgesics continue to be a unique and necessary part of effective pain management for some patients. FDA is also cognizant of serious safety concerns associated with both higher strength and higher daily doses of opioid analgesics…" FDA brought in two of their expert Advisory Committees to participate in the discussions: the Drug Safety and Risk Management Advisory Committee (DSaRM) and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC). Committee members include prominent respected physicians and academics knowledgeable in these areas. FDA provided a detailed background package to assist committee members in preparing for the meeting. The background package included a statement acknowledging that "Unlike other approved analgesic products, most opioid analgesics have no maximum dose because there is no ceiling effect for analgesia. Further, along the range of doses that have been used clinically, no particular dose of any opioid has been determined to be a cutoff point between safe-for-use or unsafe-for-use." The background package offered a comprehensive and balanced presentation of the facts, issues, and trends associated with high-dose opioid use and safety…an excellent starting point for the meeting agenda.

Senior FDA leaders Dr. Judy Staffa, PhD, RPh and Dr. Sharon Hertz, MD facilitated a robust two-day discussion on the nitty-gritty details about the use and safety of high-dose opioids that are critical to the future care of many of our FIPR members. Two FIPR members, Kristen Ogden and Anne Fuqua, attended the meeting and spoke on behalf of intractable pain patients. It was clear to them that these FDA officials recognized the value of these medications for IP patients and the wide range of effective doses.

What did FIPR attendees think?

"I attended the entire meeting and came away hopeful. FDA officials and the expert advisors expressed much concern about ensuring access for those who really need and benefit from high-dose opioids! Specific illnesses were mentioned, including Adhesive Arachnoiditis, Reflex Sympathetic Dystrophy/Complex Regional Pain Syndrome, and Ehlers-Danlos Syndrome."

- Kristen Ogden

"I came away feeling that the committees not only wanted to make the right decision, but also understood the value of opioids in the management of intractable pain. I never left another meeting feeling this way."

- Anne Fuqua

Clearly, the docket comments and letters submitted by patients and advocates to FDA and other agencies when opioid policy issues have been on the table have had an impact and contributed to FDA's

decision to hold this meeting. Kudos to all the patients, family members, and advocates who traveled to FDA in Silver Spring, MD for the July 9, 2018 meeting on chronic pain. Change doesn't come about as quickly as we would like, but your participation is making a difference!

FDA staff made it clear at the beginning that no decisions would be made during the meeting. "The FDA will not issue a final determination on the issues at hand until input from the advisory committee process has been considered and all reviews have been finalized." While we can't predict the outcome of this meeting, we do believe FDA staff and their expert advisors are listening. That is good news!

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