

## The U.S. Pain Foundation organizes patient-led listening session on osteoarthritis at the FDA

### BACKGROUND AND OVERVIEW

On Aug. 7, a group of three U.S. Pain Foundation representatives with osteoarthritis (OA) and one caregiver joined Director of State Advocacy & Alliance Development Shaina Smith to speak about the challenges of the disease before senior officials at the U.S. Food and Drug Administration (FDA) in Silver Spring, MD. The goal of the listening session was to provide FDA officials insight into the experiences, perspectives, unmet needs, and treatment priorities of people living with OA, particularly those individuals who have not found adequate relief from current therapies.



Each U.S. Pain volunteer had the opportunity to describe their personal experiences with the disease and associated chronic pain. Key takeaways from the patient listening session included:

- OA as a burdensome disease with an enormous impact on quality of life
- Challenges in identifying and accessing appropriate treatment options and adequately managing chronic pain
- The complexities in understanding the risks and benefits of available pain therapies
- The need for new, safer and more effective alternative approaches in pain management with low potential for misuse or abuse

OA, a debilitating joint disease that occurs when cartilage between the joints breaks down, is one of the nation's most widespread chronic diseases. According to Centers for Disease Control and Prevention (CDC), 23 percent of all adults in the United States have arthritis. Of the over 100 types of arthritis, OA is the most common and

most pervasive. Its symptoms include chronic pain, stiffness, and swelling of the joints, which makes it difficult to perform life's daily activities.

As indicated during the patient listening session, the management of OA and chronic pain is complex. Those diagnosed with OA turn to a range of therapies, including diet and lifestyle changes, physical therapy and exercise, dietary supplements, over-the-counter medications, and medically prescribed options, such as injections, prescription pain medication, or medical foods. Some patients are advised to try pain-relieving medical devices or surgery to replace the joint altogether.

## **PATIENT REPRESENTATION**

- Rebecca Kavanaugh Stubbles
- Kelly Lewis
- Robert Boehler
- Cindy Boehler, Caregiver

## **PARTNER ORGANIZATIONS**

- U.S. Pain Foundation (session sponsor and leader)
- Arthritis Foundation (participated via conference line)
- National Council on Aging (participated via conference line)
- National Kidney Foundation (participated via conference line)
- HealthyWomen (participated via conference line)

## **FDA OFFICE REPRESENTATION** (24 officials attended in-person and via conference call)

- Office of the Commissioner
  - Patient Affairs Staff
  - Office of Clinical Policy and Programs
- Center for Biologics Evaluation and Research (CBER)
  - Division of Clinical Evaluation and Pharmacology/Toxicology, Office of Tissues and Advanced Therapies
- Center for Drug Evaluation and Research (CDER)
  - Division of Nonprescription Drug Products, Office of Drug Evaluation IV, Office of New Drugs

- Division of Pulmonary, Allergy, and Rheumatology Products, Office of Drug Evaluation II, Office of New Drugs
- Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences
- Patient-Focused Drug Development Staff
- Professional Affairs and Stakeholder Engagement Staff
- Center for Devices and Radiologic Health (CDRH)
  - Office of the Center Director
  - Anterior Spine Devices Branch, Division of Orthopedic Devices, Office of Device Evaluation
- Center for Food Safety and Applied Nutrition (CFSAN)
  - Office of Dietary Supplement Programs
  - Office of Nutrition and Food Labeling, Office of Foods and Veterinary Medicine

## HIGHLIGHTS OF PATIENT DISCUSSION

Listening session participants prepared statements and answered questions from the FDA. The main statements and discussion points are grouped by general subject below. Highlighted in italics are actual statements quoted from listening session participants, all of whom live with OA. The patient experience dialogue was supplemented with results from a U.S. Pain Foundation survey.

### ***1. OA is a burdensome disease with a significant impact on daily activities***

Out of the more than 100 forms of arthritis (*CDC 2016*), OA is the most pervasive. As such, it is one of the most common causes of chronic pain. *The American Journal of Therapeutics* noted in its 2008 report that chronic pain associated with OA causes limitations in activities of daily living, reduced or disturbed sleep, issues in social relationships, increased anxiety and depression, and decreased overall quality of life. This is corroborated by CDC-analyzed data from the National Health Interview Survey, where 43% of adults with arthritis (all forms) reported arthritis-attributed activity limitations (*Barbour 2017*), and 27% of adults with arthritis (all forms) reported severe joint pain (*Barbour 2016*). According to another study, from 2013-2015, adults with arthritis reported 180.9 million total lost work days, which constituted 34 percent of reported lost work days for any medical condition.

Unsurprisingly, this pain and disability takes a toll. In a study published in *Arthritis Care & Research*, researchers found that one in three Americans living with arthritis aged  $\geq 45$  years also have anxiety or depression (Murphy 2012).

*“My pain was so severe in my hands that I could not grasp my steering wheel. To drive, I had to put my hands through the holes in the steering wheel and use my arms to steer...My main profession has always been to work for non-profit organizations that help people, but my OA symptoms made it so I could no longer perform the responsibilities necessary to remain in the nonprofit sector...Outside of the medical costs relating to my chronic condition, osteoarthritis has cost me physically and emotionally. I have gained 140 pounds since 2011 as the result of trying new medications. I’m not able to properly function on a daily basis because of the serious pain I experience everywhere on my body. I’ve also been diagnosed with depression, which, combined with the challenges of osteoarthritis, can result in days where my quality of life is significantly impacted.” [Kelly Lewis]*

*“Despite all of these pain management strategies, I was never pain free. The intensity of my pain had been mediated but certainly was still an ever-present distraction.” [Bob Boehler]*

## **2. OA is associated with comorbidities and other complications**

The U.S. Pain Foundation noted that there are presently no treatments for OA that modify disease progression. Currently available treatments are palliative and unreliably pain reducing. Additionally, OA is more common in older age groups and is complicated by coexisting conditions such as diabetes, heart disease, kidney disease, cancer, and other complex diseases. This raises several challenges, especially in the elderly, such as polypharmacy and comorbidities, which can influence and limit the choice of treatment for OA.

*“I am just one of the many people who live with osteoarthritis and have other underlying medical issues that makes treatment planning very complicated. ...After the initial consult and a few visits with my pain doctor, we decided to start a series of steroid injections. They were very*



*helpful, but only temporarily. Unfortunately, they exacerbated my previously very controlled diabetes which I had controlled for 20 years with just one pill a day, along with diet and exercise. Because of the steroid injections, I had to start insulin.” [Rebecca Kavanaugh Stubbles]*

*“In June 2013, a second operation was planned to do a foraminotomy at C6-7. The pre-op revealed kidney failure from NSAID abuse. I was immediately hospitalized for four days for hydration, observation and more tests. Finally, on the seventh of July, the surgery was done to remove the arthritic stenosis causing nerve impingement...Following that second operation, it was discovered that the chronic use of NSAIDs had damaged my kidneys and reduced their function to 46% (now 38%) which is technically stage three kidney disease.” [Bob Boehler]*

### **3. Commonly used therapies come with risks**

Not all individuals diagnosed with OA are able to utilize commonly recommended treatment options by physicians. NSAIDs, for example, are contraindicated for a growing subpopulation of Americans diagnosed with both OA and chronic kidney disease. These unique individuals are at high risk for heart attack, stroke, and gastrointestinal bleeding. When a patient is no longer able to use NSAIDs, acetaminophen may be prescribed, but according to patient listening session participants, this option may not be as effective.

After failing over-the-counter regimens, physicians may prescribe opioid therapy for their OA patients, an option which carries safety risks and potential for misuse. It is clear that when NSAIDs are not an option, there is a crucial need for finding alternatives.

*“We decided that over-the-counter non-steroidal anti-inflammatory drugs, or NSAIDs, were the best course of treatment for me when I had extreme OA flare-ups. This over-the-counter option was very effective for me for years. Then, I was diagnosed with chronic kidney disease, stage 3 B. The stages of this disease are ranked from one to five, with five being the worst; I was already at 65% kidney failure...As you may be aware, NSAIDs can put a lot of stress and work on the kidneys...I started to see*

*a nephrologist, a kidney specialist, and he immediately had me stop any over-the-counter NSAIDs. Because of my chronic kidney disease, my nephrologist suggested acetaminophen to alleviate my OA pain, which by itself was not in the least effective. My pain levels only went down from a 5 to a 4.5. ...My primary doctor then suggested tramadol, a Schedule IV opioid taken orally. It was extremely effective, but sadly this prescription therapy has its own set of side effects such as opioid-induced constipation, nausea, headaches, and dizziness. All of these side effects led to needing more medication to counteract the tramadol.” [Rebecca Kavanaugh Stubbles]*

*“I am unable to take non-steroidal anti-inflammatory drugs or NSAIDs because I have chronic kidney disease, stage 3, despite this over-the-counter option being one of the most common ‘go-to’ treatments.” [Kelly Lewis]*

*“Following that second operation, it was discovered that the chronic use of NSAIDs had damaged my kidneys and reduced their function to 46% (now 38%), which is technically stage 3 kidney disease. I sought out a pain management specialist and he prescribed vicodin. It was effective to the degree that I could tolerate the chronic ache and stabs of sharp pain in my lower back. However, it did require an extra effort to stay mentally sharp enough to perform a wide variety of my duties on the job. ...I suffered from all the usual side effects of opioid use, such as constipation and brain fog. As a coach, I was expected to drive the bus for my team, but that was no longer allowed due to my use of narcotics.” [Bob Boehler]*

#### **4. Alternatives to opioids and NSAIDs are not well-covered by insurance**

All attendees expressed that complementary and integrative options--such as water therapy, physical therapy, massage, etc.-- have proven to be effective pain management tools. These options are typically low-risk and promote long-term health and functional improvements. Unfortunately, many integrative therapy options are not well-covered by health plans. Health coverage challenges, in addition to medical costs, result in overall financial burdens for individuals with OA.

*“I also had been researching other treatment options and found a few, like water therapy, was and still is a wonderful pain management therapy. I also tried massage therapy, but found it was still very pricey even with some limited coverage from our health insurance.” [Rebecca Kavanaugh Stubbles]*

*“To manage my pain levels, I was advised by my primary doctor, rheumatologist and pain management doctor to attend warm water therapy 3-4 times a week; each session costs three hours of my day and is not covered by insurance. I’ve been attending warm water therapy since November of last year. For me, this expense is huge since I am unable to work from all of my disabling conditions, including OA.” [Kelly Lewis]*

Another option discussed by attendees was medical foods, specially formulated food products used under the supervision of a medical professional. This therapy is intended to assist the dietary management of individuals with certain chronic diseases, including osteoarthritis. Distinct from both drugs and supplements, medical foods are beginning to emerge as one treatment option for patients, but lack of awareness or knowledge surrounding this therapy amongst healthcare professionals and insurance companies has led to varied -- often insufficient -- health coverage across the country.

*“While trying to find the right combination to relieve my OA pain, my pain specialist had suggested something I’d never heard of before: medical food...To my surprise, this therapy worked for me. It was not a quick, overnight relief that someone may experience with say an opioid, but after three to four weeks of consuming it, it was apparent that this therapy option was working for my osteoarthritis.” [Rebecca Kavanaugh Stubbles]*

*“The pain management physician suggested that I try a food medicine [medical foods] for relief from pain and reduction of the arthritic inflammation in the joints of my spine. Within two months, my pain symptoms - and side effects of the drugs - were gone. Being completely pain free and a fully awake at all times rejuvenated me and improved every aspect of my life. [Bob Boehler]*

## 5. Invasive and surgical therapies are risky, and not necessarily beneficial

More intrusive treatment options for OA, such as steroid injections, nerve ablation, and implanted devices, are available and may offer some relief. The patients involved in the listening session, noted that these options only temporarily alleviated their pain and discomfort. (Of course, these individuals are just a sample of the OA patient population; some individuals with OA may find relief from more involved interventions.) Invasive treatments also come with risks and side effects.

*“After the initial consult and a few visits with my pain doctor, we decided to start a series of steroid injections. They were very helpful, but only temporarily. My pain doctor then suggested radio frequency ablation. An electrical current is produced by a radio wave and used to heat up a small area of nerve tissue. We tried that and it has been very effective, but that too is not without the possibility of side effects and other complications due to it being a very invasive procedure, usually done under conscious sedation.” [Rebecca Kavanaugh Stubbles]*

*“Cortisone shots were hit or miss; their side effects left me with sleepless nights from the pain, grogginess throughout the day, and weight gain... I had a spinal cord stimulator implanted in my back three years ago, under the recommendation by my pain management doctor. While it helped my sciatica for about one year and Raynaud’s syndrome numbing experienced in my feet, it did not ease the OA pain felt in my back.” [Kelly Lewis]*

*“In his efforts to resolve the cause of my pain in the lumbo-sacral region, the pain management specialist also regularly performed lumbar rhizotomies, epidurals and cortisone injections while increasing the doses of Vicodin, Norco, Butrans and Nucynta, as prescribed in that sequence.” [Bob Boehler]*

## 6. U.S. Pain Foundation’s survey results underscore complexity and severity

The U.S. Pain Foundation collected data in 2018 from its extended patient population. Out of the 2,119 participants, 768 respondents live with osteoarthritis. Some key findings from OA survey included:

- 58% of respondents rated their daily pain as 7 or more on a scale of 1 to 10



- 70% listed their work status as “disabled”
- 73% have lived with pain for more than 10 years
- More than 98% live with a comorbid condition
- The most common pain medications tried at any point were opioids (93%), NSAIDs (82%), muscle relaxants (80%) and topical agents (80%).

## CLOSING REMARKS

All of the speakers expressed their gratitude for the opportunity to share their chronic pain journey with the FDA. U.S. Pain Foundation requested that the FDA continue its open dialogue with patient-centered organizations and provider groups through future listening sessions.

In summary, suggestions for improving the health and lives of people with OA include:

- Increased insurance coverage for a wider range of therapy options for OA
- More research into new OA products that would halt or slow disease progression
- More comprehensive, coordinated care for people with OA to help them navigate the challenges of controlling their condition (e.g. case managers)
- The development of more educational resources for OA patients, to help them better understand their disease and advocate for proper care
- Encourage the creation of safe, alternative treatment therapies, both pharmacologic and integrative
- Continue developing ways that patient and provider groups can cultivate a partnership with the Department of Health and Human Services in an effort to gain new information relating to osteoarthritis pain and ways to effectively manage it

*“...it’s important that decisionmakers like yourselves hear stories like mine so that when you have the opportunity to endorse more research or bring new treatment options to the public, you can remember the unique and unmet needs of osteoarthritis patients like me.” [Rebecca Kavanaugh Stubbles]*

*“Today I am asking that the FDA and policymakers consider the unique challenges for osteoarthritis patients who live with multiple conditions and*

*have been diagnosed at a young age. Those within the chronic pain community live with pain each moment of every day. I am here today, sharing my story, but I am doing so with a pain level which may cause others to stay in bed. I'm fighting through the pain because it's important that you hear from individuals like me who have yet to find that combination of therapies to manage my osteoarthritis and want nothing more than to enjoy a fraction of our lives." [Kelly Lewis]*

*"...my presence here today is only to be a witness to the efficacy of some alternatives." [Bob Boehler]*

**DISCLAIMER**

*Discussions in FDA Disease Listening Sessions are informal. All opinions, recommendations, and proposals are unofficial and nonbinding on FDA and all other participants. This report reflects statements and experiences from actual patients with osteoarthritis (OA) and chronic pain and their caregivers who presented in this FDA listening session as well as from participating patient advocacy organizations with perspectives of patients and caregivers for whom they advocate. To the extent possible, the terms used in this summary to describe specific manifestations of OA and associated chronic pain, health effects and impacts, and treatment experiences, reflect those of the participants. This report is not meant to be representative of the views and experiences of the entire OA patient population or any specific group of individuals or entities. There may be experiences that are not mentioned in this report.*

**FURTHER INFORMATION**

Please contact Shaina Smith, Director of State Advocacy & Alliance Development, U.S. Pain Foundation, at [shaina@uspainfoundation.org](mailto:shaina@uspainfoundation.org) or 800-910-2462. U.S. Pain Foundation is the largest 501 (c)(3) nonprofit organization dedicated to serving people with chronic pain.

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