

The Voice of the Patient

A series of reports from the U.S. Food and Drug Administration's (FDA's)
Patient-Focused Drug Development Initiative

Chronic Pain

Public Meeting: July 9, 2018

Report Date: March 2019

Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

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Introduction

On July 9, 2018, the Food and Drug Administration (FDA) held a public meeting to hear patient perspectives on chronic pain, views on treatment approaches, and challenges or barriers to accessing treatments for chronic pain. FDA was particularly interested in hearing from individuals who experience chronic pain that is managed with analgesic medications such as opioids, acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), antidepressants, other medications, and non-pharmacologic interventions or therapies. FDA conducted the meeting as part of the agency's Patient-Focused Drug Development (PFDD) initiative, an effort to systematically gather patients' perspectives on their condition and available therapies to treat their condition.¹

Overview of chronic pain

Chronic pain is defined as either pain that persists for more than three months or pain that lasts more than one month beyond the normal healing time for the underlying cause of the pain. Chronic pain can be divided based on the origin of the pain; whether it is nociceptive, neuropathic, or mixed. Nociceptive pain is due to direct tissue damage and can be subdivided into visceral pain (such as pain due to kidney stone or post-operative pain) or non-visceral pain (such as pain after orthopedic surgery or musculoskeletal pain). Neuropathic pain is due to primary damage or dysfunction in the peripheral or central nervous system (such as diabetic peripheral neuropathy, postherpetic neuralgia, or pain after stroke). Pain may be characterized by how the feeling manifests (e.g., aching, throbbing, tingling, burning); location (localized or diffused); radiation to other body parts; temporal aspects (intermittent or constant); onset (gradual or sudden); trigger factors; and severity. Pain is a subjective experience and is described differently by each individual in each condition. Chronic pain can have physical, functional, social, and emotional impacts. It can cause weakness, sensory changes, difficulty with mobility, sleep issues, emotional stress, anxiety, isolation, or depression. Chronic pain conditions affect more than 100 million adults in the United States² and many of those patients experience high-impact chronic pain that interferes with daily life or work activities.³

The goal of chronic pain treatment is to decrease and manage the pain to improve physical function, social and emotional wellbeing, and quality of life. In most cases, chronic pain cannot be eliminated completely. There are multiple therapeutic approaches for the treatment of chronic pain, including prescription and non-prescription medications, invasive and non-invasive medical procedures, cognitive behavioral therapy, occupational and physical therapy, and complementary and alternative therapy such as acupuncture, herbal medicine, hypnosis, tai chi, biofeedback, etc. Types of prescription medications often used to manage chronic pain include muscle relaxants, non-steroidal anti-inflammatory drugs, antidepressants, anticonvulsants, and opioids. Medical procedures for the management of chronic pain include pain pumps, spinal cord stimulators, peripheral nerve stimulators, and nerve blocks. Non-drug therapies and lifestyle modifications such as exercise, physical therapy, and acupuncture may also be utilized for the management of chronic pain. There are multiple options and considerations to determine the optimal treatment for chronic pain in each individual case. Treatment may focus on certain options or utilize a multidisciplinary treatment approach to provide an integrated management plan that includes different treatment options, both pharmacologic and non-

¹ More information on FDA's PFDD initiative can be found here:

<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm579400.htm>.

² "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research" can be found here:

https://www.ncbi.nlm.nih.gov/books/NBK91497/pdf/Bookshelf_NBK91497.pdf

³ <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6736a2-H.pdf>

pharmacologic. The focus of a multidisciplinary approach is on individual assessment of each case, to provide a comprehensive and collaborative treatment plan to manage pain and improve quality of life. To achieve optimal results, health care providers and patients should work together to set goals for each patient and develop a treatment plan. There are some potential barriers to the treatment of chronic pain. The appropriate treatment options may not be available or accessible for patients. For example, multidisciplinary pain programs may not be available in rural areas or there may be difficulty with availability of some medications. Cost or type of insurance coverage could be another limiting factor in treatment plan, for both pharmacologic options and non-pharmacologic options. Time or duration of therapy may be a barrier in some cases; for example, it may not be feasible for patients to take time off from work to attend multiple therapy sessions. Side effects of the pain medication are other important potential barriers in treatment of pain. Long term effectiveness and tolerability of pain medication is another factor that should be considered in management of chronic pain.

There are numerous, important, public health issues related to chronic pain. The focus of this meeting is to obtain input from patients, as the main source who is suffering from chronic pain. Patients, caregivers, and patient advocates are experts in providing the information about the impact of pain on their lives and about their treatment goals. Collecting information from patients' experiences, provides an opportunity for the FDA to understand patients' perspectives on chronic pain and to enhance regulatory decision-making.

Meeting overview

This meeting provided FDA with the opportunity to hear directly from patients, caregivers, and other stakeholders about their perspectives on and experiences with chronic pain. The discussion focused on two key topics: (1) symptoms and daily impacts of chronic pain that matter most to patients, and (2) patients' and families' perspectives on current approaches to treating chronic pain. The questions for the meeting discussion (Appendix 1) were published in a [Federal Register notice](#) that announced the meeting.

For each topic, a panel of individuals who experience chronic pain (Appendix 2) shared comments to begin the dialogue. Panel comments were followed by large-group facilitated discussions inviting comments from other individuals who experience chronic pain and caregivers in the audience. An FDA facilitator led the discussion, and a panel of FDA staff (Appendix 2) asked follow-up questions. Participants who joined the meeting via the live webcast (referred to in this report as web participants) also contributed comments. In addition, in-person and web participants were periodically invited to respond to polling questions (Appendix 3), which provided a sense of the demographic makeup of participants and how many participants shared a particular perspective on a given topic.

Approximately 120 individuals who experience chronic pain or caregivers of individuals who experience chronic pain attended the meeting in-person. Approximately 300 individuals who experience chronic pain or caregivers accessed the live webcast and many provided input. Meeting participants (in-person and webcast) varied in gender, race, age, type of chronic pain, and experiences with chronic pain. Most participants had experienced chronic pain for more than 10 years. Participants also varied in their experiences and overarching perspectives on approaches to managing chronic pain, but collectively have used almost every pharmacologic and non-pharmacologic treatment available for chronic pain. Based on the meeting discussion, it appears that in-person participants in general have found opioids to be an effective pain management approach for their condition when compared to other available treatments. Although participants at this meeting may not fully represent the overall population of individuals who

experience chronic pain, the input received reflects a range of experiences with and perspectives on chronic pain and chronic pain management approaches.

To supplement the input gathered at the meeting, individuals who experience chronic pain and others were encouraged to submit comments on the topic to a public docket,⁴ which was open until September 10, 2018. A total of 2,450 comments were submitted to the public docket, the majority of which included either individuals who experience chronic pain, caregivers, or patient advocacy organizations.

More information, including the archived webcast and meeting transcript, is available on the meeting website: <https://www.fda.gov/drugs/newsevents/ucm603093.htm>.

Report overview and key themes

This report summarizes the input shared by individuals who experience chronic pain, caregivers, and other stakeholders during the meeting or through the webcast. It also includes a summary of comments submitted to the public docket. To the extent possible, the terms used in this report to describe specific symptoms, impacts, or treatment experiences. The perspectives described in this report reflect the words used by in-person participants, web participants, or docket commenters. The report is not meant to be representative of the views and experiences of any specific group of individuals or of the larger population of individuals living with chronic pain. Accordingly, there may be symptoms, impacts, treatments, or other aspects of chronic pain not included in this report.

The input from the meeting and docket comments underscore the diversity of experiences with chronic pain, the complexity of selecting an appropriate treatment, and the broader challenges individuals who experience chronic pain face in accessing care, treatment, and support. Several key themes emerged from this meeting:

- The health effects of chronic pain are pervasive and wide ranging. Participants frequently described living with daily unrelenting chronic widespread pain, in addition to persistent fatigue, sleep issues, and other debilitating health effects. Many shared fears that their chronic pain would worsen over time.
- Chronic pain affects all aspects of individuals' lives. Many participants described severe limitations and adaptations needed to perform at work or at school, and to care for themselves and their family. Many also described the devastating loss of meaningful relationships with family and friends due to their chronic pain. Participants shared the emotional toll of experiencing stigma, social isolation, and financial challenges of treatment, and fears of living with an often-misunderstood condition.
- Many participants emphasized the difficulty in achieving pain relief and that effective management of chronic pain requires a multidisciplinary approach tailored to the needs of the individual. Some stressed the need for a holistic approach to treating chronic pain, including lifestyle management, diet and exercise, and psychosocial techniques, in addition to medical treatments. They expressed varying perspectives on the desired outcomes of treatment. For most, the shared focus, however, was to improve their daily quality of life.

⁴ A *docket* is a repository through which the public can submit electronic and written comments on specific topics to U.S. federal agencies such as FDA. More information can be found at www.regulations.gov.

- Many participants identified several challenges and barriers to accessing treatments to manage their chronic pain. They highlighted growing stigma on the use of opioid analgesics and the impact of stigma on their interactions with healthcare providers and others when seeking treatment, particularly being perceived as “an addict.” A common experience shared during the meeting is that of an individual living with chronic pain who has had successful pain management in the past using a stable dose of opioid analgesics but who now has severely worsened pain resulting from reduced access to opioids because of a change in their doctor’s practice or willingness to prescribe opioids.
- Participants often emphasized the need for increased awareness and understanding of chronic pain across the medical and policymaking community. Participants offered perspectives on how to better help individuals with chronic pain manage their condition, expressing hope for progress in the development of effective non-opioid treatment options.

The patient input generated through this PFDD meeting and the public docket comments strengthens FDA’s understanding of the impact of living with chronic pain and the treatments currently used to manage chronic pain. FDA staff will carefully consider this input when discussing development programs and when assessing products under review for marketing approval. This input may also be of value to FDA’s work more broadly to address the complex opioid public health crisis. For example, it may inform efforts to reduce the risk of misuse and abuse of opioids while still enabling appropriate access to those patients who have legitimate medical need for these medicines.

Topic 1: Symptoms and Daily Impacts of Chronic Pain that Matter Most to Patients

The first topic discussion focused on gathering perspectives on the symptoms and daily impacts of chronic pain on individuals’ health and daily life. FDA was particularly interested in understanding how participants describe the symptoms and impacts of chronic pain in their own words. FDA was also interested in learning how chronic pain affects individuals’ ability to perform daily activities normally and as fully as they would like to.

Four patient panelists (Appendix 2), all females living with chronic pain, described their experiences to start the discussion. One panelist was unable to attend the meeting in-person due to a pain flare up⁵, and the FDA facilitator presented prepared comments on her behalf. Panelists reported having lived with chronic pain for periods ranging from a few years to decades. The panelists’ opening comments provided a range of perspectives on how their chronic pain manifests and impacts their daily life. Panelists described the depth of challenges they face with a range of chronic pain symptoms, and the debilitating impact their symptoms have on their ability to perform daily activities. One panelist considered her chronic pain fairly well-managed, two panelists considered their chronic pain somewhat managed, and one panelist considered her chronic pain not managed well. Participants also described the significant frustration, stress, fear, and stigma they have experienced because of their condition and the challenges they face in accessing appropriate treatment.

⁵ While traveling to the meeting, she was stuck in traffic and was in too much pain to complete the trip.

During the large-group facilitated discussion that followed the panel discussion, nearly all individuals and caregivers in the audience indicated by a show of hands that their experiences, or those of their loved ones, were reflected in the panelists' comments. The remainder of this section summarizes in more depth the input from in-person and web participants on the topics related to the symptoms and impacts of chronic pain.

Perspectives on how chronic pain symptoms typically manifest

During the discussion, pain was described in unique ways, including: "tight, hard pressure," "electrical shock," burning, severe muscle spasms, and headaches. One participant described their pain as "jellyfish stings," while another stated that their pain was like a "red hot poker being shoved into [their] hip." In a polling question (Appendix 3, Q7), participants were asked to identify how their chronic pain symptoms typically manifest. Participants expressed variation in the frequency, intensity, and onset of their chronic pain. The following examples illustrate the experiences shared during this discussion by participants.

- "My chronic pain is both nebulous and rebellious. It doesn't have a specific daily routine or even an hourly location. It roams to different parts of my body like a nomad."
- "It [pain] ranges in intensity just as much it ranges in location."
- "This pain has pushed me to my breaking point. One night [while riding in the car] my mind was so overwhelmed with that pain, I reached up and tried opening my door so I could jump out of the car. This was not a suicide attempt. It was an overwhelming thought. Maybe if I could just make something else hurt it would take my mind away from the pain I was feeling. My pain is so severe my mind thought the only way to cope with the pain was to slam my body on to a hard surface at 65 miles per hour."
- "Very severe headache that feels as though [my spouse's] skull is being crushed. It is as though someone made a mold of [my spouse's] whole head, made it about a quarter of an inch too small, and then forced [my spouse's] head into it anyway."
- "I've been in chronic pain so much I really don't know what it feels like to not be in pain."
- "When you live with chronic pain you can be in severe pain but physically look okay. You learn to live with a higher level of pain."
- "An 8 on my [pain] scale would be when the nerve pain is so bad it feels like all of my skin has been removed and my joints have been packed with a combination of glass... So I guess on my scale, a 9, which I've never experienced, would be childbirth, and then a 10 would probably be like if your arm got ripped off and you pass out..."

In a polling question (Appendix 3, Q8), participants were asked to identify how much time over the course of a typical day they spend in pain. Most participants indicated that they spend all day (24 hours) in pain of varying intensity. During the discussion, participants also identified a range of activities that could trigger their pain or cause "flares" during which pain increases in intensity. For example, one participant stated, "One wrong move and it felt like there was a hatchet in my spine." Another participant stated, "[I am in] constant fear of anything touching me, like people who are huggers or waitresses who like to pat you on your shoulder." Participants also indicated stress, hormonal changes (e.g., spike in estrogen levels), clothing, and weather as triggers for their pain. Throughout the discussion, participants highlighted the variability and unpredictability of the severity and frequency of their pain as burdensome aspects of their pain. One participant noted, "I might be able to give my son a high five one day and be fine...another day, give my daughter a hug and have my rib go out of place."

Fatigue and difficulty sleeping

Many participants identified fatigue as a significant health effect of their chronic pain. As one participant stated, “fatigue feels like I’ve run into a brick wall running at full speed and I’m trying to get up but just so exhausted.” A web participant commented, “[fatigue] is unpredictable and intense.” During the discussion, many participants highlighted the overlap between their chronic pain and fatigue. Participants noted this overlap as causing difficulty in determining the root cause of the health effects they experience. For example, some meeting participants described experiencing fatigue due to living in constant chronic pain. As one participant described, “Fighting chronic pain is tiresome.” Other participants associated fatigue as a symptom of their underlying condition or a trigger for their chronic pain “flare-up.” One participant described the overlap as, “No sleep because [of] pain, no rest because [of] pain, not staying awake because [of] fatigue and pain.” Another participant noted that, “the fatigue at times is as burdensome or even more than the pain.”

Some participants shared their experiences with difficulty falling asleep, staying asleep, or experiencing restful sleep. Similar to fatigue, the participants highlighted the overlap between their chronic pain and their difficulty sleeping. One participant stated, “My pain has kept me up at night for most of my adult life.” A web participant shared, “I rarely sleep well. I wake up 8-12 times a night from pain in various parts of my body.” Many participants detailed experiences with the cyclic relationship between pain, fatigue, and sleep. One web participant stated, “I have gone for well over a decade on an average of two broken hours of light sleep per night. It does nothing to help the cycle of chronic pain and fatigue.” As another participant shared, “Fatigue comes from fighting the pain and not being able to sleep.”

Other health effects

In addition to fatigue and sleep issues, participants highlighted other health effects of their chronic pain that have a significant impact on their daily lives. These health effects include sweating, nausea, instability (e.g., falling), and cognitive symptoms such as memory and attention issues. One participant shared, “your memory and thoughts are affected due to the severity of the pain.” Another participant stated, “...increasing pain [leads] to increasing brain fog.”

Overall impacts of chronic pain on daily life

Throughout the meeting, both in-person and webcast participants described in rich detail the impact that chronic pain has on daily life, including:

- **Emotional Impacts.** The majority of participants who spoke referenced that chronic pain has taken an emotional toll on their lives. These participants described being physically and emotionally isolated, and having strong feelings of hopelessness, anxiety, and frustration. For example, one young adult shared that chronic pain “has caused me to feel lost,” while another participant added, “the emotional burden thereby creates more physical pain.” Several participants in the room and many others on the web shared that they or someone they personally know had contemplated or attempted suicide. One participant shared, “I’ve been in a psychiatric unit of a hospital for two weeks because of suicidal thoughts because of pain.” Another participant stated, “A good day is a day I do not research assisted suicide or look into moving to a state that has legalized suicide for chronically ill patients.” Further discussion on participants’ comments on suicide in the context of access to treatment is provided in the Topic 2 section below.

- **Impact on relationships.** Participants described the impact that chronic pain had on their personal relationships. As one participant shared, “chronic pain robs us of normal daily functions, family interactions, and relationships.” Many participants shared their difficulties in socializing and making plans that were often cancelled due to the severity and unpredictability of their chronic pain. For example, one participant stated, “pain keeps you a prisoner in your own body and your bedroom while your family is downstairs laughing, playing games...” Others shared their frustrations that family and friends did not understand the physical and emotional limitations of living with chronic pain. One participant shared, “family members forget that she’s sick. They get mad. They tease her. They undermine her situation. Her mom tells her to get over it.” A web participant noted, “My extended family and some friends believe I am just addicted and not actually sick because it said so on the news.” This highlighted the perspective also voiced by other participants that chronic pain is often invisible to others around the individual with chronic pain. Another web participant commented, “Friends and family no longer come around because it’s too hard to see us hurting.”
- **The ability to perform activities.** Participants expressed how chronic pain has affected their ability to perform activities. Several described being bedridden because of their chronic pain. Others highlighted the difficulty in caring for themselves. For example, one participant shared, “I don’t even wear pants anymore because... [of] pained fingers and zippers.” Others commented on their inability to care for others. One participant shared, “He [my son] didn’t put me down as an emergency contact because he knows I can’t be there for him.” Several participants reflected on how it is not just the individual with chronic pain that is impacted by the condition, but their families as well. One participant shared, “my pain does not just affect me, it affects my husband, who always has his guard up and ready to help me all the time. My son, who knows how bad the pain can be if I am touched...”
- **Impact on career.** Many participants shared that their chronic pain has made it difficult or impossible to work or have a career. One participant shared, “I used to be a massage therapist...now I can barely rub lotion on my own hands.” Another participant stated, “I went from being a mom, wife, and an executive at the peak of my career, to spending nearly every moment in the day bed in my family room.” Several participants added that the cognitive symptoms associated with their chronic pain, such as their ability to concentrate or stay focused, also impacts their ability to work. As one participant described, “Your mind is distracted by your pain.”
- **Stigma and discrimination.** Many participants highlighted the impact of stigma and discrimination, particularly in their interactions with healthcare providers and others. Participants described being perceived as “an addict,” or “drug-seeker.” A few participants also discussed the impact of stigma in their current workplace or when pursuing career opportunities. One web participant stated, “I get accused of ‘faking’ my pain at work all the time!” Another participant shared, “...if I admitted how sick I was, even though I went to work, I wouldn’t be able to get a job.”
- **Burden of managing daily life and worry about the future.** Many participants described the significant burden of managing day-to-day while living with chronic pain. One participant shared, “I have to go to my doctor’s office to get the piece of paper for my opioid prescription and then take that to the pharmacist and then they fill the pain prescription. However, what happens when I’m in a flare and I can’t drive because I’m in so much pain?... And if I’m in bed

and can't get out of bed and run out of pain medications? There's just a serious gap there.” Many participants also shared a sense of anxiety and uncertainty about the future, particularly in the face of the challenges and barriers to accessing treatment for their chronic pain (discussed further in the Topic 2 section below). A few participants focused on their concerns regarding the progression of their underlying condition which would lead to worsening severity of their chronic pain.

Topic 2: Patient Perspectives on Treatments for Chronic Pain

The second topic discussion gathered perspectives from individuals with chronic pain on their experiences with approaches to pain management. Four panelists (Appendix 2) provided comments to start the dialogue, including three women and one man. All four of the panelists were adults between 30 to 60 years old who have lived with chronic pain for many years. The underlying conditions and type of chronic pain varied among the panelists. Panelists shared their experiences with a range of therapies, including opioids, antidepressants, anticonvulsants, ketamine infusions, non-steroidal anti-inflammatory drugs and a range of non-drug therapies including transcutaneous electrical nerve stimulation, medical marijuana, psychosocial therapies, and other lifestyle modifications. Out of the four panelists, only two described their chronic pain as fairly well-managed with their current management approaches; however, one of the two indicated that he still had flares that were not well-managed. Panelists also described the significant burden of a trial and error therapy regimen, making difficult decisions on benefits versus adverse effects of treatments, and access issues to opioids.

In the large-group facilitated discussion that followed, participants indicated by show of hands that their experiences (or those of loved ones) were reflected in the panelists’ comments. Throughout the discussion, individuals who experience chronic pain and caregivers discussed their experiences with prescription and non-prescription medications, invasive and non-invasive medical devices, and non-drug therapies such as behavioral and physical therapies. Overall, almost all the participants expressed that their approach to managing their chronic pain is multidimensional. In addition to medication, participants described a variety of other approaches used to manage their condition, which included medical devices, complementary or alternative therapies, behavioral changes, and physical therapy. Several participants stressed that their comments represent the treatment and management approaches which worked best for them personally and may not be applicable to all individuals with chronic pain, considering the varied underlying conditions in the chronic pain community.

Perspectives on current treatments

Participants described a range of treatment approaches to manage their chronic pain, often detailing a complex process of finding a suitable approach to pain management. Participants provided diverse perspectives on a range of treatment goals for pain management. Many participants expressed that for them an effective treatment was one that helped reduce the severity and/or frequency of their chronic pain enough to “manage” or be “functional” day-to-day.

Participants’ perspectives on the benefits and downsides of their therapies, as well as what they would look for in an ideal treatment, are summarized below.

Opioids

During the meeting, opioids were the most frequently mentioned prescription pain relievers. Participants reported a wide range of experiences and perspectives on opioids. Most participants with experience with opioids noted that opioids have been effective for them and have significantly increased their quality of life when compared to other available treatments. In describing their experiences with opioid medications, many focused on the benefits of treatment. For example:

- “I will never be pain free but with these medications the pain is manageable enough that I can usually leave the house for an hour or two without having to lie down.”
- “I take opioid medication every day so that I can get comfortable enough so that I can actually go to sleep...”
- “I was able to do activities of daily living that I think anybody would want to have in their life be able to accomplish”
- “Opioids allow me and my husband [to] be ‘normal’ persons again. Without them we would both be bed-bound.”

A few participants touched upon their experiences with side effects of opioids, including nausea, vomiting, constipation and sleepiness. A less common but present perspective was an acknowledgement of the potential for dependence or addiction but also a feeling that they did not have good alternatives to opioids. Several participants highlighted the difference between dependence and addiction and emphasized that while they might be dependent they are not addicted to opioids.⁶ Several participants also shared that the pain relief from opioids outweighs their risk of and/or experience with side effects. Other participants stated that they experience no side effects from their opioid medications. For example, one web participant commented, “Opioids have been the one consistent medication that has no side effects and allows me to live my life in a productive manner.” Several participants emphasized that incorporating opioids in their pain management approach was a “last resort” after seeing reduced or little to no pain relief from other medical or non-medical therapies.

Other medical therapies

Participants also described their experiences with other prescription and over-the-counter medicines. Several participants discussed their experiences with anticonvulsants, particularly Lyrica (pregabalin) and Neurontin (gabapentin). A few participants described anticonvulsants as providing successful pain management, while other participants said anticonvulsants provided tolerable pain management, but not completely eliminating pain. Participants also described their experiences with acetaminophen, prescription nonsteroidal anti-inflammatory drugs, antidepressants, implantable medical devices (e.g., spinal cord stimulator implants, infusion pumps), non-invasive medical devices (e.g., Transcutaneous electrical nerve stimulation (TENS)), topical patches, over-the-counter medications (e.g., ibuprofen) and others. Overall, these were described as varying widely in effectiveness. Several participants also shared that continuing treatment has been difficult due to side effects, even when the treatment was effective. Participants also highlighted the burden of the trial and error process to find an effective management approach which fits their needs, with respect to pain management and adverse effects.

⁶ The input from this meeting may underrepresent people who have experienced addiction or other adverse effects stemming from their medical treatment of opioids.

Non-medical therapies

Meeting participants, in-person and via webcast, emphasized the importance of non-medical therapies in the management of their chronic pain. In a polling question (Appendix 3, Q11), participants identified dietary and herbal supplements, diet modifications, cannabinoids (such as medical marijuana), complementary and alternative therapies (such as acupuncture, massage, relaxation, meditation and biofeedback), physical or occupational therapy, mobile applications, and counseling or psychotherapy. Overall, participants noted some level of relief from these therapies. A few participants identified other products, such as kratom and ketamine infusions, that they considered to support their management of chronic pain. Meeting participants stressed “no one size of treatment fits all.”

Treatment downsides

In a polling question (Appendix 3, Q12), participants were asked to identify what they considered to be the most burdensome or concerning treatment downsides. Difficulty accessing treatment was identified by a majority of the participants as a burdensome or concerning downside. Additional perspectives on loss of access or reduced access to opioids are described in the section below.

During the discussion, participants also highlighted other treatment downsides, including bothersome short-term side effects. Participants described experiences with a range of short-term side effects including nausea, vomiting, sweating, skin rashes, weight gain, hair loss, sleepiness, sexual dysfunction, anxiety, depression and cognitive effects (e.g., difficulty focusing, memory loss). Some participants commented that their therapies had initial success but became less effective with time. Several participants also commented on the cost of treatment, including out-of-pocket costs for treatments not covered by insurance.

Perspectives on loss of access or reduced access to opioid analgesics

Participants who reported using opioid analgesics described the challenges and barriers in accessing these treatments and the stigma they face. A common experience shared during the meeting is that of an individual experiencing chronic pain who has had successful pain management in the past with stable use of opioid analgesics, but who has reduced access to opioids because of a change in their doctor’s practice or willingness to prescribe opioids. Participants described several factors that led to a loss of access or reduced access to opioids, including:

- **Government regulations and policies.** Participants commented on government regulations and policies that impact doctors, pharmacists, and insurance companies. Participants shared their belief that these policies exacerbate the day-to-day burden of accessing their medications, including being treated like an “addict,” having a difficult time finding a doctor who will prescribe the medication or a pharmacist who will fill the prescription, and a lack of understanding by the insurance companies.
- **Reduced dosing or forced taper.** Participants commented on the reduced access to opioids. Several participants described instances when their doctor won't prescribe as many , pharmacist won't dispense as many, or insurance won't cover as many pills. A few participants also commented on being willing to taper but, when their pain returned, they were not allowed to return to their prior dose.

- **Medical abandonment.** Many participants commented that their doctor is no longer practicing or no longer prescribing opioids and they could not find a new doctor. A few participants also commented on their experiences where he or she violated part of their pain contract or was no longer seen by their doctor for some other reason.

Participants also described in detail the devastating impact that the loss of access or reduced access to opioids has on their daily lives, including:

- **Poor quality of life.** Participants commented on increased pain, withdrawal, disability, isolation, inability to work, inability to care for self or others, stigma and discrimination, anxiety and depression, and self-harm and suicide as a result of loss of or reduced access to opioids. For example:
 - “[The doctor] said ‘I was not worth her losing her license over.’ She started weaning me off my pain meds (where I was stable) which resulted in my attempting suicide because the pain was so unbearable.”
 - “I had a good quality of life up to the point that the doctor said no he didn’t want his license taken away. Where do I go? What do I do? Suicide is the only treatment left to me.”
 - “In the name of saving me from only potentially suffering because of narcotic use, forced delays and changes to my treatment have denied me quality of life through the majority of my almost 40 years and the entirety of my child's 13 years, by both worsening and adding to my medical conditions in permanent ways. I now take higher doses of stronger controlled substances, while getting less effective treatment from them, AND have an increased physical/chemical dependence on them.”
 - “Chronic pain patients feel we have three options now: 1. Live in debilitating pain, 2. Go to the streets, 3. [Commit] suicide.”
- **Turning to alternatives.** Several participants described their experience of having reduced access to opioids as leading to using legal but less effective therapies, while for several others not having access to legal channels for opioids led to illegal drug use. A participant shared, “I have been reduced to 25% of my original...Choice is between suicide and risking incarceration...” A few participants commented that the illegal drug use in turn has led to incarceration or death. One participant stated, “My brother died after being cut-off, & my daughter as well - they both went out to the street, both are dead...”
- **Worry about future.** Participants described anxiety or fear that their doctor will reduce their prescription in the future. A few participants also commented on their worry about addiction but also feel they don’t have effective alternatives. Another common theme comes from chronic pain patients who have not actually experienced a loss or reduction in access to opioids but worry that it will occur in the future. One participant shared, “...those who have medicine are terrified it’s going to be taken away at the next pharmacy visit, at the next doctor’s visit, at any possible moment.”

Improving the management of chronic pain

Participants provided a range of perspectives on areas which could be improved to assist management of chronic pain. Meeting participants stressed that enhanced management of chronic pain begins by

improving the government and medical community’s understanding of chronic pain and increased awareness of the debilitating impacts of their condition. In discussion of an ideal treatment, participants stressed the desire for effective non-opioid treatment options to manage their chronic pain and the need for continued research.

Summary of Comments Submitted to the Public Docket

FDA received approximately 2,450 comment submissions to the public docket that supplemented the Patient-Focused Drug Development meeting on chronic pain. Most of the comments were submitted by patients with chronic pain, with a few comments from patient caregivers. FDA also received comments from multiple advocacy organizations and professional societies, including the Academy of Managed Care Pharmacy, Advanced Medical Technology Association, American Physical Therapy Association, Arachnoiditis Society for Awareness and Prevention, Families for Intractable Pain Relief, Global Healthy, Living Foundation, Hemophilia Federation of America, Interstitial Cystitis Association, and the Restless Leg Syndrome Foundation. FDA also received results from a survey conducted by an individual patient advocate in cooperation with National Pain Report.

Overall, the comments received in the docket reflected the experiences and perspectives shared at the July 2018 meeting. The following is a high-level summary of comments provided on chronic pain conditions, impacts, and current treatments, focusing on experiences or perspectives that were not raised or addressed in detail at the meeting.

Submitted comments on symptoms and daily Impacts of chronic pain that matter most to patients

Commenters identified over 100 conditions they experienced, most of which were directly associated with their chronic pain, and some of which were comorbid conditions. The table below shows the approximate counts of the 20 most frequently-mentioned conditions.

Table 1: Approximate Count of Docket Comments that Describe Conditions Causing Chronic Pain

Condition	Number ⁷
Spinal Pain	724
Post-surgical Pain	558
Arthritis (Including osteoarthritis and rheumatoid arthritis)	455
Fibromyalgia	339
Back Pain	302
Cancer	194
Post-injury/trauma/accident	168
Bone pain / condition	159
Canal stenosis	148
Joint Pain	144

⁷ Some comments mentioned multiple conditions.

Neuropathy	139
Hip Pain / Replacement	136
Complex regional pain syndrome	103
Headache & Migraine	98
Kidney Disease	81
Ehlers Danlos Syndrome	78
Autoimmune Disorder	67
Adhesive Arachnoiditis	63
Lupus	62
Neuralgia	57
Neck Pain	53
~100 Other Conditions	933

The comments described a wide range of symptoms, manifestations, and levels of severity for chronic pain. Many of the descriptions of chronic pain in the comments were similar to those discussed in the meeting, including:

- Characteristics of chronic pain** – Commenters shared in vivid detail how they experienced their chronic pain. Commenters described their pain in a variety of ways, including: “throbbing,” “aching,” “stabbing,” “burning,” “shooting,” “squeezing,” and “grinding.” Commenters also highlighted the severity of their chronic pain, with most commenters emphasizing that their pain affects them significantly. Many commenters described being nearly or entirely disabled because of their pain, with some calling it “excruciating,” “intractable,” or “horrific.”
- Duration of pain** – Many of the commenters described being in near-constant pain. Some commenters said their pain symptoms were intermittent, but the majority stated that their pain was largely always present unless they were on medication. Additionally, many commenters said that they had been living with constant pain for 10 or more years, with some saying they had lived with pain for most of their lives. Others described a slow worsening of their pain over time and expressed concern about the possibility of worse pain in the future.
- Impact on sleep and fatigue caused by pain** – Many commenters discussed how their chronic pain has significantly impacted their ability to sleep, leading to fatigue and exhaustion. Commenters often stated that they could not sleep longer than a few hours at a time, with one commenter saying, “I haven’t slept through the night in longer than I can remember.” Several commenters identified fatigue and lack of sleep as one of the factors preventing them from “living a normal life.” Other commenters echoed this, stating that fatigue made it more difficult for them to manage their chronic pain.

Submitted comments on the overall impact of chronic pain on daily life

The docket comments reflected the input received from meeting participants on the debilitating impact of chronic pain on every aspect of patients' lives. Commenters described a wide range of emotional, social, and physical burdens they experienced because of their condition, including:

- **Emotional Impacts.** Commenters frequently said that their chronic pain had a significant impact on their emotional well-being. Many commenters stated that their chronic pain was causing depression, anxiety, and other negative impacts. Commenters called their chronic pain “demoralizing,” “exhausting,” and “stressful.” Others described feelings of hopelessness and fear for the future, saying that their chronic pain showed no signs of improvement and they felt that they had no options. As one participant put it, “[I ask] myself: ‘Is this all there is? Day after day, month after month, year after year of this nonstop pain?’” Several participants also shared that they or their loved ones had either had suicidal thoughts or had attempted suicide in the past because of their chronic pain.
- **Impact on relationships.** Commenters described in detail how their chronic pain had affected their ability to maintain personal relationships. Many commenters stated that their chronic pain had negatively impacted friendships, marriages, and family life. Commenters discussed how chronic pain limited their ability to go on social outings, to play with children, to participate in their community, and to stay in touch with friends. Several commenters highlighted the unpredictability of their chronic pain, saying that they frequently had to cancel plans at the last minute when their pain is particularly bad. Commenters highlighted feeling isolated and unable to spend time with their families, such as one commenter who shared: “I feel as I've been a failure as a mother, grandmother, as well as a wife because of my pain.” Another stated that she had been in pain so long that her son “doesn't know what it is like to have a Mom that isn't in pain.”
- **The ability to perform activities.** Commenters also addressed how their chronic pain had limited their ability to perform activities and be physically active, sharing similar perspectives to those participating in the meeting. Some commenters stated that their chronic pain left them entirely or mostly bedridden. Many commenters said that they could not leave their home or care for themselves as a result of their chronic pain. One commenter said that even taking a shower “would put me in tears because of the pain.” Several commenters stated they could no longer play sports, go for walks, maintain hobbies, dress themselves, prepare food, or perform a number of other basic activities. One commenter shared her difficulty with conducting daily tasks, saying “I struggle with showering, lifting my arms to comb my hair, doing anything that requires any muscles.” Other commenters described their quality of life as being “diminished” or “destroyed” by their chronic pain.
- **Impact on work, school, and careers.** Commenters frequently discussed the impact that chronic pain has had on their academic and professional careers. Many commenters said that they had to stop working or had lost their jobs because of their chronic pain. Several commenters said that they had been forced to go on disability due to the severity of their condition. Some commenters said they were able to work part time because of the medications but expressed concern about the possibility of losing their jobs if their condition worsened or they lost access to their medication. Many commenters said that they wanted to work but were physically

unable to, such as one commenter who shared, “The inability to be productive or work has damaged my sense of self-worth... I really miss working and get jealous of my husband when he leaves in the morning.”

- **Stigma and discrimination.** Many commenters stated that they had faced stigma or social discrimination as a result of their condition or their treatment needs. Commenters frequently stated that the “invisible” nature of their disease had led to them being treated as “drug seekers” or “drug addicts” by healthcare professionals and others. Commenters said that doctors often did not understand or believe that they were experiencing severe pain. Others said that they felt discriminated against by the healthcare system and were not being treated like patients with legitimate healthcare needs. One commenter described her frustration by saying, “I hate that I am being treated like a drug abuser when I am just trying to make my life more manageable on a daily level.” Other commenters expressed similar sentiments.

Submitted comments on current treatments for chronic pain

The submitted comments reflected a similar broad approach to treating chronic pain, including medical products, non-medical products, alternative therapies, and other treatments. The comments overall were similar to the perspectives shared by meeting participants.

Perspectives on current treatments

Commenters’ experiences with prescription and non-drug therapies emphasized that managing chronic pain can be difficult, and many patients experience challenges with finding a treatment regimen that works for them. More detail is providing below.

Opioids

As with the meeting, opioids were the most frequently mentioned prescription pain relievers in the docket comments. Many of the commenters shared that they were either currently taking opioid medication or had done so in the past. Commenters largely echoed the perspectives of the meeting participants, stating that opioids have been effective in managing their chronic pain and increasing quality of life. Several commenters said that they had tried a wide range of treatments, but that their pain had only responded to opioids. Some said that their opioid medication gave them “enough control over the pain that I can focus on my work and enjoy life and feel that life is worth living.”

Perspectives on loss of access or reduced access to opioids

Most commenters also emphasized that they experienced challenges in accessing opioid treatment. Commenters reflected similar perspectives to those patients participating in the meeting, highlighting several factors which they described as restricting their access to opioids. Many participants stated that they felt government policies and approaches to regulating opioid prescribing had contributed to difficulty in accessing opioid medication. Commenters frequently said that government policies on opioids were harming chronic pain patients, and that they felt that they could not access “legitimate pain medications.” Commenters also reiterated that they are having difficulty finding doctors willing to prescribe them opioid medication. Many commenters attributed this to changes in government policy, saying that their doctors are now “afraid of consequences” or of “losing their license” if they prescribe opioid medication. Several commenters stated that they had been on the same treatment plan with the

same doctor for years, but that their doctor no longer was willing to continue that treatment plan. Commenters described other barriers to access, such as increased testing, patient contracts, and being “tapered” off current treatment regimens.

Commenters also described the impact that losing access to opioid medications has had on their health. Commenters shared similar perspectives to meeting participants, emphasizing the reduced quality of life and worry for the future. One commenter who had recently lost access to medication stated that, “without the medication, I’m just barely surviving. My pain is excruciating, and I never get a break.” Another described their experience by saying, “The care I used to receive for my pain doesn’t exist anymore. My pain used to be taken seriously, treated as a vital sign, now it’s treated as an inconvenience, an annoyance, a red flag of addiction or something that if treated can end that doctor’s career.” Many commenters expressed similar perspectives.

Other therapies

In addition to opioids, commenters described using a wide range of other therapies to treat their condition. These ranged from additional pain medications (including both prescription and OTC drugs), to surgical procedures, to complementary or alternative therapies. Some of the medical products mentioned included acetaminophen and other NSAIDs, anti-inflammatories, anticonvulsants, antidepressants, implantable medical devices, topical patches, and others. Some of the other therapies mentioned included acupuncture, diet and behavioral changes, mobile applications, supplements, physical therapy and exercise, cannabinoids, and kratom.

Overall, commenters highlighted the significant impact chronic pain has on their health and daily lives. Commenters discussed a range of experiences with opioids and other treatment options, with many describing opioids as effective in managing their chronic pain. Commenters also emphasized that they continue to experience challenges with accessing opioid medication, and that lack of access to opioids can negatively impact their health and quality of life.

Conclusion

Patients are experts in living with their disease or condition, including their experience with the treatments they have used to manage their condition. FDA is grateful to the patients and their loved ones who so thoughtfully, generously and courageously shared their personal stories of living with chronic pain during the meeting and through the public docket. Through this meeting, FDA learned more about what matters most to individuals and caregivers impacted by chronic pain. The perspectives shared helped strengthen our understanding of the challenges and barriers individuals face accessing various treatments for chronic pain. This meeting provided valuable insights to inform our opioid policies and advance our efforts to develop better therapies. FDA shares the desire and commitment expressed by the chronic pain community to advance the development and appropriate use of safe and effective treatment options for managing chronic pain.

Appendix 1: Meeting Agenda

Public Meeting on Patient-Focused Drug Development for Chronic Pain

July 9, 2018

10:00 – 10:05 am	Welcome Meghana Chalasani <i>Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), FDA</i>
10:05 – 10:10 am	Opening Remarks Theresa Mullin, PhD <i>Associate Director for Strategic Initiatives, CDER, FDA</i>
10:10 – 10:25 am	Background on Chronic Pain and Treatment Options Sepideh Haghpanah, MD <i>Division of Anesthesia, Analgesia and Addiction Products (DAAAP), CDER, FDA</i>
10:25 – 10:35 am	Overview of Discussion Format Meghana Chalasani <i>OSP, CDER, FDA</i>
10:35 – 11:05 am	Topic 1 Panel: Symptoms and Daily Impacts of Chronic Pain Topic 1: Symptoms and daily impacts that matter most to patients. A panel of patients and patient representatives will provide comments to start the discussion.
11:05 – 12:00 pm	Large-Group Facilitated Discussion on Topic 1 Patients and patient representatives in the audience are invited to add to the dialogue.
12:00 – 1:00 pm	Lunch
1:00 – 1:05 pm	Afternoon Welcome Meghana Chalasani <i>OSP, CDER, FDA</i>
1:05 – 1:35 pm	Topic 2 Panel: Patients' Perspectives on Treatments for Chronic Pain Topic 2: Patient perspectives on current approaches to chronic pain. A panel of patients and patient representatives will provide comments to start the discussion.
1:35 – 2:30 pm	Large-Group Facilitated Discussion: Topic 2 Patients or patient representatives in the audience are invited to add to the dialogue.
2:30 – 2:45 pm	Break
2:45 – 3:20 pm	Large-Group Facilitated Discussion: Topic 2 Continued
3:20 – 3:50 pm	Open Public Comment
3:50 – 4:00 pm	Closing Remarks Sharon Hertz, MD <i>Director, DAAAP, CDER, FDA</i>

Discussion Questions

Topic 1: Symptoms and daily impacts of chronic pain that matter most to patients

1. How would you describe your chronic pain? (Characteristics could include location, radiation, intensity, duration, constancy or intermittency, triggers etc.)
2. What are the most significant symptoms that you experience resulting from your condition? (Examples may include restricted range of motion, muscle spasms, changes in sensation, etc.)
3. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your chronic pain? (Examples of activities may include work or school activities, sleeping through the night, daily hygiene, participation in sports or social activities, intimacy with a spouse or partner, etc.)
4. How has your chronic pain changed over time? (Considerations include severity and frequency of your chronic pain and the effects of chronic pain on your daily activities)

Topic 2: Patients' perspectives on current approaches to treatment of chronic pain

1. What are you currently doing to help treat your chronic pain? (Examples may include prescription medicines, over-the-counter products, and non-drug therapies)
 - a) How has your treatment regimen changed over time, and why? (Examples may include change in your condition, change in dose, or treatment side effects)
 - b) What factors do you take into account when making decisions about selecting a course of treatment?
2. How well does your current treatment regimen manage your chronic pain? (Considerations include severity and frequency of your chronic pain and the effects of chronic pain on your daily activities)
3. What are the most significant downsides to your current treatments, and how do they affect your daily life?
4. What challenges or barriers to accessing or using medical treatments for chronic pain have you or do you encounter?
5. What specific things would you look for in an ideal treatment for your chronic pain?

Docket Information: We encourage you to submit your written comments to the docket by September 10, 2018: <https://www.regulations.gov/document?D=FDA-2018-N-1621-0001> or go to www.regulations.gov and search for: **chronic pain patient-focused drug development**.

Appendix 2: Patient and FDA Panel Participants

Patient Panel, Topic 1

- Amy
- Katie
- Tien
- Debbie

Patient Panel, Topic 2

- Lindsay
- Louis
- Rose
- Hilary

FDA Panel

- Sepideh Haghpanah, Division of Anesthesia, Analgesia, and Addiction Products (DAAAP), Center for Drug Evaluation and Research (CDER)
- Sharon Hertz, DAAAP, CDER
- Janet Maynard, DAAAP, CDER
- Theresa Mullin, Office of the Center Director, CDER
- Elektra Papadopoulos, Clinical Outcome Assessments Staff, CDER
- Michelle Tarver, Office of the Center Director, Center for Devices and Radiological Health
- Amy Taylor, Division of Pediatric and Maternal Health, CDER
- Gerald Willett, Division of Bone, Reproductive and Urologic Products, CDER

Appendix 3: Meeting Polling Questions

Patient-Focused Drug Development Meeting on Chronic Pain

Demographic Questions

1. Where do you live?
 - a. Within Washington, D.C. metropolitan area (including the Virginia and Maryland suburbs)
 - b. Outside of the Washington, D.C. metropolitan area

2. Which statement best describes you?
 - a. An individual who experiences chronic pain
 - b. A family member or caregiver of an individual(s) who experiences chronic pain
 - c. An advocate for individuals who experience chronic pain

We will ask that the remainder of the questions be answered by participants who responded “a or b” to Question 2, or by participants who are answering on behalf of a loved one with chronic pain.

3. What is your/your loved one’s age?
 - a. Younger than 18
 - b. 18-29
 - c. 30-39
 - d. 40-49
 - e. 50-59
 - f. 60 – 69
 - g. 70 or greater

4. Do you/your loved one identify as:
 - a. Male
 - b. Female
 - c. Other

5. How long have you/your loved one experienced chronic pain?
 - a. Less than 1 year
 - b. 1 years to 2 years
 - c. 2 years to 5 years
 - d. 5 years to 10 years
 - e. More than 10 years
 - f. I’m not sure

6. What type of chronic pain do you/your loved one experience? **Check all that apply.**
- a. Cancer Pain
 - b. Post-surgical or post-traumatic pain
 - c. Neuropathic (nerve) pain
 - d. Headache
 - e. Orofacial (mouth, jaws, face) pain
 - f. Visceral (organ) pain
 - g. Musculoskeletal pain (such as arthritis)
 - h. I don't know
 - i. Other

Question for Topic 1: Symptoms and daily impacts of chronic pain that matter most to patients

7. How do your chronic pain symptoms typically manifest? **Check all that apply.**
- a. I have periods without pain
 - b. My pain appears suddenly
 - c. My pain appears subtly
 - d. My pain is intermittent
 - e. I always have pain and the intensity changes over time
 - f. I always have pain and the intensity doesn't change over time
 - g. My pain worsens over time
 - h. I don't know
 - i. My pain manifests in another way
8. Over the course of a typical day, how much time do you spend in pain?
- a. Several minutes
 - b. Less than 4 hours
 - c. Between 4 to 12 hours
 - d. More than 12 but less than 24 hours
 - e. All day (24 hours)
9. What are the most bothersome impacts of your chronic pain on your daily life? **Please choose up to three impacts.**
- a. Ability to participate in or perform activities (such as work, participation in sports or social activities, driving, make or keep plans for activities, etc.)
 - b. Ability to fall asleep or stay asleep
 - c. Ability to concentrate or stay focused
 - d. Ability to care for self, family, and others
 - e. Impacts on relationships
 - f. Stigma or embarrassment
 - g. Social discrimination
 - h. Emotional impacts (such as mood, fear, hopelessness, etc.)
 - i. Other impacts not mentioned

Questions for Topic 2: Current approaches to treatment of chronic pain

10. Have you ever used any of the following therapies to manage your chronic pain? **Check all that apply.**

- a. Transdermal or topical patches (such as lidocaine)
- b. Acetaminophen, prescription nonsteroidal anti-inflammatory drugs (NSAIDs such as diclofenac), or over-the-counter products (such as ibuprofen and naproxen)
- c. Opioid medication
- d. Antidepressant drugs (such as Elavil (amitriptyline), Prozac (duloxetine), Effexor (venlafaxine))
- e. Non-invasive medical devices (such as transcutaneous electrical nerve stimulation or TENS)
- f. Anticonvulsant medications (such as neurontin (gabapentin) or Lyrica (pregabalin))
- g. Implantable medical devices and/or surgical procedures (such as spinal cord stimulator implants, implantable infusion pumps, or surgical destruction of nerves)
- h. Other therapies (drugs or medical devices) not mentioned
- i. I'm not using any therapies (drugs or medical devices)

11. Besides the therapies mentioned previously, what else are you doing to manage your chronic pain? **Check all that apply.**

- a. Dietary and herbal supplements
- b. Diet modifications and behavioral changes (such as changes to alcohol and tobacco use)
- c. Cannabinoids (such as medical marijuana)
- d. Complementary or alternative therapies (such as acupuncture, massage, relaxation, meditation and biofeedback)
- e. Physical or occupational therapy
- f. Mobile applications
- g. Counseling or psychological treatment
- h. Other therapies not mentioned
- i. I am not doing or taking any therapies to treat my chronic pain

12. For the therapies you use, what do you consider to be the most burdensome or concerning downsides? **Please choose up to three answers.**

- a. How the therapy is administered (such as a pill, injection, or invasive procedure)
- b. The frequency and length of treatment
- c. Difficulty in accessing treatment (for example, insurance or cost)
- d. The treatment only provides minimal benefit or is effective only for a short-term
- e. Bothersome short-term side effects of the treatment (such as nausea or fatigue)
- f. Concern about serious risks of the treatment
- g. Uncertainty about long-term effects of treatment
- h. The risk of developing drug abuse and addiction
- i. Other downsides not mentioned