<u>Discussion – Issues Affecting Chronic Pain Patients</u>

April 22, 2019

<u>Definition of Pain - Acute, Chronic & Intractable</u>

Pain is defined as physical suffering or discomfort caused by illness or injury

Acute Pain typically lasts less than three months and is usually of a sudden onset; will usually go away on its own.

Chronic Pain persists most days or every day for longer than 3-6 months and extends beyond the normal period of healing. For some chronic pain patients, pain can last a lifetime and is a disease in its own right. Chronic intractable pain is severe, excruciating and constant, and is not curable by any known means. It is disabling and can cause a bed or house-bound state and early death if not adequately treated, usually with opioids and/or interventional procedures.

Statistics/Effects of pain

- An estimated 50-100 million people in the U.S. have some form of chronic pain, making it a public health concern and epidemic; up to 20% have chronic *intractable* or *high-impact* pain that affects their daily lives and activities.
- The financial and societal burden of chronic pain costs the United States an estimated \$635 billion *annually* in terms of lost productivity and health care costs.
- Pain is the leading cause of disability in the United States, yet less than 2% of the NIH's budget goes to pain research.
- Chronic pain becomes a permanent feature of patients' lives leading to depression, sleep disturbance, fatigue, lack of physical functioning, career and social relationships; family and friends are also adversely affected.

Addiction vs. Chronic Pain

- Addiction and Chronic Pain are both chronic diseases in and of themselves, but they are separate and distinct. <u>Addiction</u> is the compulsive use and mental craving of a substance despite harmful consequences with an inability to stop; failure to meet work, social, or familial obligations; chasing a "high." Conversely, chronic pain patients using an opioid (or other) medication for a legitimate medical reason may become *physically dependent* on a medication. <u>Physical Dependence</u> is when the body adapts to the drug, and causes physical symptoms if stopped (i.e., withdrawal). Patients using opioid medication for a legitimate purpose will become physically dependent, but this doesn't mean they are addicted. Appropriate medical use of opioids will have *benefits* to health and function unlike addiction, which sees a *negative* impact in health, function, career and relationships with the *abuse* of opioids.
- The risk of addiction is very low (less than 1%) for legitimate chronic pain patients who use opioids long-term. Overwhelmingly, addiction arises from recreational NOT therapeutic use of these drugs, yet addiction and chronic pain are wrongly being grouped into one category both as addiction when one has nothing to do with the other.
- Chronic pain patients who are prescribed opioids long-term must sign a pain contract with their physicians, are randomly drug tested and subject to pill counts, must use the same pharmacy and are also in a national database.

CDC Guidelines (2016) and Results on Chronic Pain Sufferers

- In response to the increasing number of drug overdose deaths in America (aka, "the Opioid Epidemic"), the CDC established controversial "voluntary" guidelines in 2016, addressed to *primary care physicians* prescribing opioids for acute and chronic pain. The Guidelines were met with sharp criticism from healthcare providers, patients, advocates, prescribers and the chronic pain community as a whole. Although the Guidelines were *voluntary*, they have been made *mandatory* in many areas, and taken on the weight of law. This has had a negative effect on the chronic pain population and their healthcare providers.
- At least 35 states have enacted some type of legislation related to prescription limits.
- The VA has been directed by Congress to make the CDC Guidelines mandatory rather than voluntary.
- Many insurers (including Medicare Part D providers) and pharmacy chains have set limits for opioid prescriptions or have refused to cover them outright, citing the CDC Guidelines as the reason.
- The Guidelines have resulted in many chronic pain patients being forcibly tapered off or being denied opioids
 altogether, resulting in drastic measures such as medication hoarding, seeking illicit drug sources and <u>suicide</u>.

- In lieu of being prescribed a stable regimen of opioids, chronic pain patients are being forced to endure invasive, risky, expensive and unnecessary procedures and surgeries, such as spinal infusions, stimulators and epidurals.
- According to a survey by Pain News Network in March 2019 of over 6,000 chronic pain patients and healthcare
 providers, the CDC Guidelines have harmed pain patients and significantly reduced their access to pain care. Of note:
 - Eight out of ten patients (80%) said they are being prescribed a lower dose or that their opioid prescriptions were stopped; many indicated they were *forcibly tapered* off opioids without an effective alternative.
 - Over 85% of patients say the Guidelines have made their pain and quality of life worse; nearly half say they
 have considered suicide because their pain is poorly treated.
 - Over two-thirds of healthcare providers are worried about being sanctioned or prosecuted for prescribing opioids; rather than risk going to prison, many have stopped treating pain, closed their practices or retired.

Recent Developments

- Despite the number of opioid prescriptions being at their *lowest level since 2003*, drug overdoses continue to *rise*. Of the approximate 47,000 overdose deaths in 2017, the greatest majority by far were NOT due to prescription opioids, but rather *illicit* drugs such as fentanyl and heroin; additionally, most deaths involving opioids predominantly involve other substances (or a combination of drugs and alcohol), making it difficult to determine the actual cause of death.
- April 9th, 2019 The FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering.
- March 2019 In a letter to the CDC, a coalition of over 300 health care providers, doctors and patient representatives writing on behalf of an organization called Health Professionals for Patients in Pain (HP3) issued a call for the CDC to clarify its guidelines, particularly when it comes to weaning patients off opioids (*letter enclosed*).
- April 10th, 2019 In response to HP3's letter, CDC Director Robert Redfield, MD, has for the first time suggested that his agency may be preparing to make changes to its controversial opioid guidelines and in his own response letter makes several clarifications (*letter enclosed*).

How Can YOU Help?

- Under international human rights standards, actions taken to combat the overdose epidemic should take the needs
 of chronic pain patients into account; medically necessary and appropriate pain treatment should be a RIGHT.
 Legislation should follow this philosophy, including addressing administrative practices that arbitrarily interfere with
 the ability of legitimate chronic pain patients who have a medical need to use opioid analgesics.
- Support efforts to educate the public (including members of Congress and presidential candidates) about the impact of the overdose crisis on legitimate pain patients; chronic pain patients shouldn't pay the price for addicts!
- Promote safer opioid prescribing practices based on the *individual needs* of patients rather than blunt cutbacks.
- Recommend the revision of the CDC Guidelines to explicitly state that patients should not be involuntarily tapered off opioids and that there is no mandated maximum dose.
- Boost the DHHS, CMS, DOL and state insurance commissioners to seek to expand insurance coverage of treatment modalities for chronic pain, including non-pharmacological interventions, alternative treatments and counseling.
- Advance efforts to keep the government out of the doctor/patient relationship.
- Promote cooperation among the CDC and DHHS in working with other relevant federal and state government agencies, state medical boards, and professional and civil society groups to ensure that clinicians (including those caring for patients on high doses of opioids) can implement the Guidelines' recommendations without having to fear unwarranted legal scrutiny, arbitrary limits or administrative barriers.
- With chronic pain a major public health concern and epidemic, champion additional hearings on pain management.
- With suicides on the rise from chronic pain (in general and with legitimate patients' inability to access opioids), endorse mental health research and treatment for those suffering with chronic illnesses and pain.
- Promote the Pain Management Best Practices Inter-agency Task Force Report, which was completed by an advisory group overseen by the DHHS and the DVA: https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf
- For additional efforts, please see "U.S. Pain Foundation Position Statement Balancing Pain Management and Opioid Reform" (statement enclosed).