NCIPC Board of Scientific Counselors
Open Session
July 22, 2020

National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
Atlanta, Georgia

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
BOARD OF SCIENTIFIC COUNSELORS (BSC)
Centers for Disease Control and Prevention (CDC)
National Center for Injury Prevention and Control (NCIPC)

Thirty-Third Meeting
July 22, 2020

Teleconference Meeting
Open to the Public

Summary Proceedings

The Thirty-Third meeting of the National Center for Injury Prevention and Control (NCIPC; Injury Center) Board of Scientific Counselors (BSC) was convened on Wednesday, July 22, 2020 via teleconference and Adobe Connect. The BSC met in open session in accordance with the Privacy Act and the Federal Advisory Committee Act (FACA).

Call to Order / Roll Call / Meeting Process / Welcome & Introductions

Call to Order

Victoria Frye, DrPh, MPH
Chairperson, NCIPC BSC
Associate Medical Professor
Department of Community Health and Social Medicine
City University of New York School of Medicine
City College of New York

Dr. Frye called to order the open session of the Thirty-Third meeting of the NCIPC BSC at 10:00 AM Eastern Time (ET) on Wednesday, July 22, 2020.

Roll Call

Mrs. Tonia Lindley
NCIPC Committee Management Specialist
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Mrs. Lindley conducted a roll call of NCIPC BSC members and *Ex Officio* members, confirming that a quorum was present. Quorum was maintained throughout the open portion of the teleconference. One conflict of interest (COI) was declared by Dr. Compton who indicated that he has long-term stock holdings in General Electric, Pfizer, and 3M Companies. An official list of BSC member attendees is appended to the end of this document as Attachment A.

Meeting Process

Arlene Greenspan, DrPH, MPH
Associate Director for Science
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Dr. Greenspan introduced Stephanie Wallace, the Writer/Editor from Cambridge Communications and Training Institute (CCTI), who she explained would record the minutes of the meeting. She requested that everyone state their names prior to any comments for the record. Minutes of the meeting will become part of the official record and will be posted on the CDC website at www.CDC.gov/injury/bsc/meetings.html. All NCIPC BSC and *Ex Officio* members were requested to send an email to Tonia Lindley at ncipcbsc@cdc.gov at the conclusion of the meeting stating that they participated in this meeting. Members of the public were placed in listen only mode until time for the Public Comment period. Dr. Greenspan indicated that Adobe Connect would be utilized to show presentations. She thanked Victor Cabada from CDC, who would be monitoring the Chat Box. She extended a special thanks to Tonia Lindley of CDC, the FACA Coordinator, who did a great job in coordinating the various components of this meeting in a complete virtual environment.

Welcome & Introductions

Victoria Frye, DrPh, MPH
Chairperson, NCIPC BSC
Associate Medical Professor
Department of Community Health and Social Medicine
City University of New York School of Medicine
City College of New York

Dr. Frye thanked everyone for their time and commitment to injury and violence prevention, recognizing that to say everyone is busy is an extraordinary understatement as everybody is struggling through these times. Given that many of them are providing clinical and public health support and programming to people who are affected by the COVID-19 pandemic, she expressed gratitude to them for taking time out of their schedules to engage in this important committee. She reminded everyone that the role of the BSC is to advise and provide counsel to leadership at the CDC and NCIPC on injury and violence prevention research and activities. She thanked and welcomed members of the public, whose engagement is very much appreciated and is critical to the BSC's role and mission. She noted that from 12:20 PM to 1:15 PM, there would be a period for public comment, at which time the operator would provide instructions to anyone wishing to make a public comment. Those unable to present their public comments during the call were invited to submit them in writing to ncipcbsc@cdc.gov before July 28, 2020 at 5:00 PM ET. There will be additional opportunities to comment on ongoing opioid activities. For those on the phone without Adobe Connect access, the presentation slides were made available at https://www.cdc.gov/injury/bsc/meetings.html.

Before beginning the meeting, Dr. Frye called for a moment to recognize the truly awful impact that the twin epidemics of COVID-19 and systemic racism are having on the country. Worldwide, COVID-19 is approaching 15 million cases according to the Johns Hopkins University (JHU) Covidtracker COVID-19 Dashboard, with nearly 4 million of those in the United States (US). In her home state of New York, they have lost over 30,000 people. People on the BSC have been treating COVID-19 patients, so she thanked them again for being present. The

other epidemic that plagues the US is systemic racism, which has manifested most recently in numerous murders of Black and African American people at the hands of police. The impact of systemic racism is seen in both COVID-19 and police brutality, or what those in injury prevention often call "structural violence." It is very clearly within the BSC's purview to address this. Dr. Frye thanked the NCIPC leadership for recognizing the BSC's calls for a focus on this issue, which is a focus in which they will engage vigorously during the August 2020 BSC meeting and that would be a focus intrinsic to the topics of this meeting related to opioid use. She called for a moment of silence to honor the memories of those who have passed as a result of these twin epidemics of COVID-19 and systemic racism.

Approval of Last Meeting Minutes

Dr. Frye referred members to the copy of the minutes provided to them from the December 4-5, 2020 NCIPC BSC meeting. With no corrections noted, Dr. Frye called for an official vote.

Motion / Vote

Dr. Floyd made a motion, which **Dr. Crawford** seconded, to approve the December 4-5, 2020 NCIPC BSC meeting minutes. The motion carried unanimously with no abstentions.

Opening Remarks from CDC's Principal Deputy Director

Anne Schuchat, MD (RADM, USPHS, RET)
Principal Deputy Director
Centers for Disease Control and Prevention

On behalf of CDC and the Leadership Team, **Dr. Schuchat** said she wanted to personally thank the BSC members, guests, and terrific staff of NCIPC who have been working hard in preparation for this meeting. Like many others, she thinks about the impact that COVID-19 is going to have on the future of public health. While they are still learning about the virus and how to save lives, it is already known that the downstream effects of the pandemic will be felt for years to come. The pandemic is affecting people across the country in many ways and is challenging CDC's programs, partners, and staff. They know that providers, hospitals, and health systems are grappling with both urgent patient care needs and maintenance of non-pandemic activities. Dr. Schuchat expressed appreciation for all of the BSC members, many of whom are working on the frontlines in their day-to-day work, for their service to CDC and for making time to join the meeting.

Beyond the pandemic, racist injustices and senseless killings also have posed unrest upon the country's communities. Racism is an ongoing public health crisis. It is critical to continue to work for racial and health equity during the pandemic. They all bear the responsibility of making the country better for themselves, communities, and future generations. Everyone can and must do better. She noted that Dr. Deb Houry would soon present some of the efforts that NCIPC has taken as immediate steps to addressing racial injustices and racial inequities. They look forward to discussing this in much more depth during the August 20, 2020 BSC meeting.

Preventing opioid overdose deaths remains a priority for the agency. The work that everyone is doing is critical. A cornerstone of that work is the *CDC Guideline for Prescribing Opioids for Chronic Pain* and ensuring that patients with pain are afforded evidence-based pain care. CDC released this guideline in 2016 to help primary care doctors provide safer, more effective care for patients with chronic pain. Since the release of the guideline, the agency has been working every angle to make sure that it is accessible, easy to understand, and seamlessly translated into clinical practice. Despite the best intensions, they have seen barriers and challenges in implementing the guideline's strategies. Unfortunately, some policies and practices derived from the guideline have been inconsistent with and often go beyond its recommendations. Appropriate implementation of the guideline supports an individualized approach to pain management that includes appropriate physical, psychological, and non-opioid strategies.

CDC has committed to updating guideline recommendations when new evidence is available. In April, the Agency for Healthcare Research and Quality (AHRQ) completed 3 systematic reviews, which include new evidence on non-pharmacological and non-opioid treatments for chronic pain. Based on the evidence, CDC has determined that an update of the guideline is warranted. Two additional systematic reviews on treatments for acute pain are underway, which will help inform the decision of whether to further expand the guidelines into the treatment of acute pain. Updating the guideline, while not a panacea for either the country's opioid or pain management challenges, will be one more step toward ensuring that patients with chronic pain receive safer and more effective pain management. CDC is committed to identifying the best evidence and partnering with other federal agencies and organizations to limit the devastation communities feel and ultimately to save lives. The agency is very thankful for the BSC's commitment to preventing prescription opioid overdose while ensuring that patients have access to safe and effective pain treatment, and also is appreciative of those who were nominated to be part of the Opioid Workgroup (OWG). This WG will help ensure broad external transparent input on the complex issues relevant for the update on the 2016 guideline.

NCIPC Director's Update

Deb Houry, MD, MPH
Director, National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Dr. Houry thanked Dr. Schuchat for joining the meeting and echoed her gratitude to all of the members of the BSC for carving out time for the NCIPC BSC meeting, acknowledging that many of them are busy responding to the COVID-19 pandemic in addition to their normal duties. She then shared updates on NCIPC's work since the last BSC meeting in December 2019. COVID-19 has impacted many people personally and professionally. CDC, like many of the BSC members, has been responding actively to COVID-19. Related to many of NCIPC's topics, it is known that strategies to prevent COVID-19 such as home quarantine or isolation may have unintended effects on the potential for physical, emotional, and sexual violence (SV) against children, partners, and other family members such as older adults; as well as increased use of substances, especially without access to addiction treatment.

NCIPC has deployed staff over 200 times to support CDC's response efforts. She personally deployed in the response from mid-March to May as a Deputy Incident Manager. Several of the Task Forces that fell under her direction included: At-Risk Populations, Health Systems, and Community Mitigation. Many of these overlapped and focused on issues related to injury and violence prevention. Since March 2020, NCIPC staff have transitioned to fulltime telework with

the exception of individuals working directly on the response and a small percentage of managers and supervisors.

NCIPC is pleased that CDC has directed specific funds to address some of NCIPC's priority areas that are impacted by COVID-19. Collectively, these projects will include a range of activities focused broadly on enhancing prevention during and after the current pandemic, as well as in future public health emergencies. NCIPC received over $32 million in COVID-19 funding. Some of the resulting activities include building capacity for suicide, adverse childhood experiences (ACEs), and intimate partner violence (IPV) prevention in Tribal communities through improved data systems and public health response and delivery of prevention efforts through virtual means; funding innovative strategies implemented by harm reduction organizations and treatment providers that help to increase access to substance use disorder (SUD) services during COVID-19; and training the injury and violence prevention workforces in state and local communities to prevent injuries and violence focusing on suicide and ACEs during COVID-19 and its aftermath. CDC continues to work closely with its partners in its response to COVID-19.

The Injury Center continues to work across a diverse range of injury and violence topics where there is a significant public health burden and where it can invest in research and resources to make an impact. NCIPC has placed a high focus on 3 areas that are high burden, high impact, and preventable: Overdose, Suicide, and ACEs. These priority areas and additional focus areas are critical to comprehensive prevention, and the focus on primary prevention must be continued. It is not enough to look at only overdose prevention for instance, which is a complex topic that may need a deeper exploration of the crosscutting issues such as ACEs.

Recent racial injustices have encouraged NCIPC to take a step back to reexamine its current programs and practices to ensure that they are justly reaching all populations, and to reassess the Injury Center's own process internally. To touch on what the Injury Center has been working on in this space and areas in which it needs to grow, NCIPC has made progress with activities such as hosting resiliency sessions with its staff to discuss recent events and areas where they have and can make progress within the Injury Center. They also have begun assessing the Injury Center's diversity among job grade series and leadership positions. This also includes recruiting an external consultant to conduct an organizational assessment on NCIPC's diversity. Leadership Team meetings have been convened to discuss ways to address inequities both in their work and within the Injury Center.

NCIPC recently approved 6 fundable proposals that address racism and inequities through activities including increasing the pipeline for minority researchers in injury and violence prevention; training and education for public safety partners to reduce African American overdose; holding National Violent Death Reporting System (NVDRS) roundtable discussions with law enforcement; and shifting structural racism through bystander actions. Other activities include discussing how NCIPC can ensure that diverse candidates are represented in its recruitment, working alongside the Human Resources Office; reviewing language in its existing funding announcements pertaining to addressing health equity and/or disparities in violence prevention research; and examining the extent to which minority-serving institutions and/or minority investigators receive funding and whether any of the funded research specifically addresses issues of race and ethnic risks. This is only the beginning of these conversations, which certainly will be ongoing. NCIPC is committed to sustainable action and changes in addressing inequalities in its work and looks forward to continuing this discussion and hearing the BSC's ideas much more in-depth during the August 2020 NCIPC BSC meeting.

In Fiscal Year 2020 (FY20), the Injury Center received a $28.8 million increase compared to FY19 funding. This includes 4 new funding lines for child sexual abuse (CSA) prevention, suicide prevention, ACEs, and firearm injury and mortality prevention research. At the beginning of 2020, NCIPC also agreed to partner with the White House Office of National Drug Control Policy (ONDCP) to manage the Drug-Free Communities (DFC) Support Program. In response to these new funding lines and its partnership with the BSC, NCIPC has created the following new funding opportunities:

- ❑ Preventing Adverse Childhood Experiences: Data to Action (PACE:D2A)
- ❑ Rigorously Evaluating Approaches to Prevent Adult-Perpetrated Child Sexual Abuse (CSA)
- ❑ Firearm Injury Surveillance Through Emergency Rooms (FASTER)
- ❑ Research Grants to Prevent Firearm-Related Violence and Injuries (R01)
- ❑ Drug-Free Communities (DFC)
- ❑ Comprehensive Suicide Prevention

Dr. Houry acknowledged the tremendous amount of interest in these funding opportunities as evidenced by the large number of applications received, which underscores the demand and need for work in these areas. NCIPC is currently in the process of reviewing applications, with funding announcements to be made later in 2020.

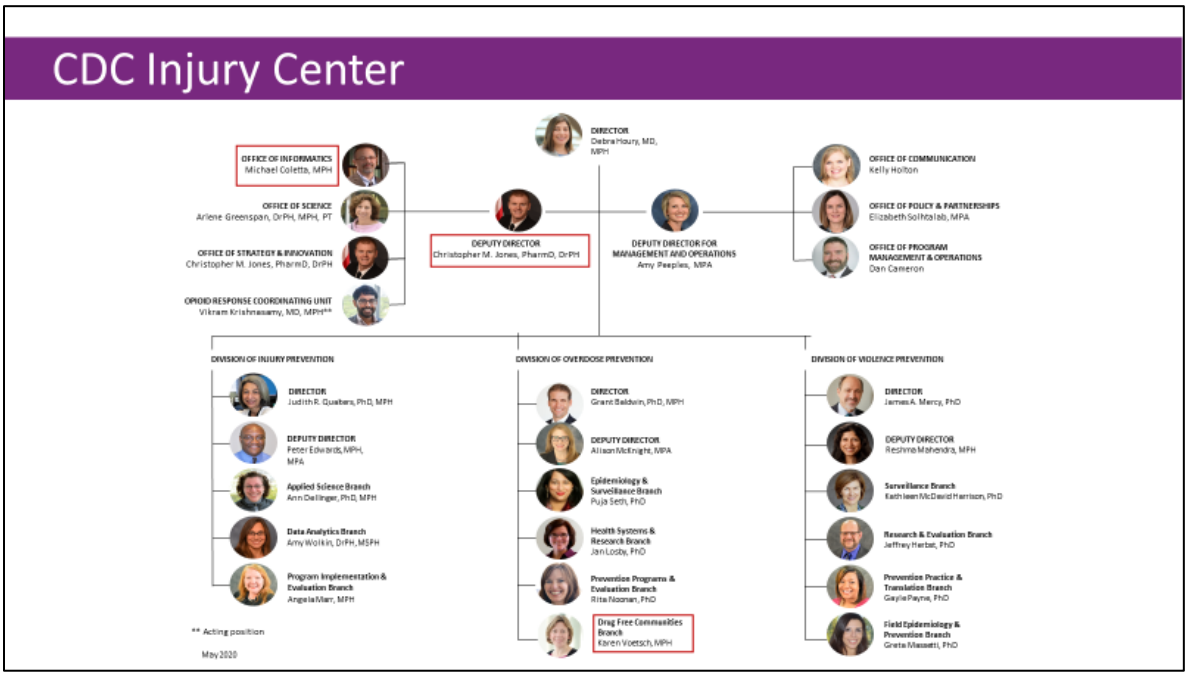
In terms of recent overdose data and work within the Injury Center, the drug overdose crisis is harming individuals, families, and communities. In 2018, there were over 60,000 drug overdose deaths. Nearly 128 people die from an opioid overdose each day. Emerging substances, such as cocaine and psychostimulants, are contributing to these overdose deaths. This introduces additional complexities into the public health response. NCIPC has been tracking these trends and examining how its prevention efforts can be broadened to address these overdoses. As the nation has been combatting the ever-changing overdose crisis, it is known that there is not just one solution and that everyone has a role to play. Recent provisional data released from the National Center for Health Statistics (NCHS) suggests that there was an increase in overdose deaths in 2019,which underscores the continued focus on prevention.

CDC's footprint in opioid overdose prevention has grown over the last few years. As previously mentioned, they are pleased to have been awarded with the administration of the DFC Support Program. This is the nation's leading effort to mobilize communities to prevent or reduce substance use among youth. Directed by the White House ONDCP, the DFC Support Program is a $101 million grant program that establishes and strengthens collaborations among various sectors of the community working to prevent youth substance use. Currently, there are more than 700 community coalitions across the country in all 50 states. These grant recipients are awarded up to $125,000 per year. The DFC Support Program presents another important opportunity to learn and work together to impact this pressing problem and focus on upstream prevention of substance use. NCIPC strongly believes that the best community-level interventions come from the communities themselves. The DFC Support Program coalitions have a tremendous amount of impact and knowledge to impart on the Injury Center, and the Injury Center has the public health expertise in crosscutting areas to share with the coalitions. NCIPC has spent the past couple of months transitioning the program to CDC and is especially thankful for ongoing support from their colleagues at ONDCP, the Community Anti-Drug Coalitions of America (CADCA), the Substance Abuse and Mental Health Services Administration (SAMHSA), and across CDC for making this transition seamless.

NCIPC's work in overdose prevention is strengthened through the Overdose Data to Action (OD2A) program. OD2A is a 3-year nearly $1 billion program that combines prevention and surveillance into one program. Dr. Houry highlighted the Injury Center's work to improve data timeliness. One example is that NCIPC is supporting non-fatal drug overdoses in 47 states and the District of Columbia (DC). Of these 48 sites, 42 are now using syndromic surveillance data to report non-fatal overdoses in 2 to 4 of emergency department (ED) visits.

The Injury Center also is enhancing its work in data science. To illustrate, Dr. Houry provided an update on two projects related to substance use. In collaboration with the Georgia Institute of Technology (Georgia Tech), NCIPC is focusing on misinformation about medication assisted treatment (MAT) and the idea that people on MAT are not in recovery and are substituting one drug for another. As part of this project, NCIPC/Georgia Tech will measure the prevalence and trends in health misinformation related to substance use and treatments, quantify the reach of this health misinformation, understand how and why this misinformation is shared, and identify ideal strategies for interventions to prevent harms related to health misinformation. A second project is a machine learning (ML) model that can be used for forecast overdose deaths using a data ensemble approach. NCIPC recently received access to National Forensic Laboratory Information System (NFLIS) data, which is a Drug Enforcement Administration (DEA) program attached with information on the illicit drug supply. This is a critical data component to any forecasting model. They are assembling the data sources and working on the programming codes. Other data that are being proposed to be included in this model include IQVIA prescribing data for opioid analgesics, National Syndromic Surveillance Program (NSSP), National Poison Data System (NPDS), Google Trends, REDDIT, Twitter, and other overdose data. In the interest of time, Dr. Houry indicated that she would be happy to present some of NCIPC's other data science work on suicide at a future meeting.

Lastly, Dr. Houry highlighted a few new leadership positions at the Injury Center as reflected in this Organizational Chart:



NCIPC was fortunate to receive approval for a second Deputy Director positions. Christopher Jones, PharmD, DrPH is now service as a new Deputy Director of the Injury Center with primary responsibilities including overseeing the science, strategy, innovation, and informatics functions of the center. NCIPC is excited about this new position as the Injury Center continues to strengthen its research and innovation and is actively recruiting for Dr. Jones' previous position as the Associate Director of the Office of Strategy and Innovation (OSI). Michael Coletta is the new Associate Director of the Office of Informatics (OI), who brings a wealth of knowledge to NCIPC from Center for Surveillance, Epidemiology, and Laboratory Services (CSELS). Karen Voetsch is the Branch Chief of the new Drug-Free Communities Branch (DFCB) within the Division of Overdose Prevention (DOP). She comes to NCIPC from the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP).

Update on the CDC Opioid Prescribing Estimates Project

Background, Methods, & Key Findings

Christina Mikosz, MD, MPH, FACP
Medical Officer & Lead, Clinical Practice Team
Division of Overdose Prevention
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Dr. Mikosz presented the results of an analysis in which the BSC was highly engaged. As shown in prior studies, opioid prescribing in the US has peaked and has begun to decline with decreases noted in the annual prescribing rate, the rate of prescriptions written for <30 days, and the average daily morphine milligram equivalents (MME) per prescription[1]. However, in 2015, prescribing rates still remained three times as high as in 1999[2] and almost four times as high as the amount distributed in Europe[3] [[1]Guy GP Jr., Zhang K, Bohm MK, et al. Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:697–704; [2]Data from 2015 represented the most recent data on prescribing practices currently available at the initiation of this project; and [3]International Narcotics Board; World Health Organization population data. By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2017].

Multiple entities throughout the years have developed clinical guidelines for opioid prescribing for both acute and chronic pain, such as the following:

- Government Agencies: CDC Guideline for Prescribing Opioids for Chronic Pain, 2016
- Medical Professional Societies: American Pain Society Guidelines on the Management of Postoperative Pain, 2017
- Health Departments: New York City Emergency Department Discharge Opioid Prescribing Guidelines, 2013
- Other Regulatory Agencies: Medical Board of California Guidelines for Prescribing Controlled Substances for Pain, 2014

Existing research has pointed to a need to reduce unnecessary opioid prescribing. Prior studies have found variation in opioid prescribing practices across clinical indications, even across multiple patients in the same institution; identified a mismatch of opioid prescribing with evidence for treatment effectiveness, such as for chronic pain; found multiple reports of unused excess opioids after surgery; and identified an association between initial days' supply and likelihood of continued opioid use. However, this is balanced against reports of undertreatment or delay in pain treatment in instances where opioid benefits may outweigh the risks.

The aims of the study on which Dr. Mikosz presented were to: 1) estimate rates and amounts of opioids prescribed for specific painful indications in outpatient settings in the US; and 2) compare qualitatively these prescribing rates against evidence-based published clinical practice guidelines. The NCIPC BSC was engaged at several points in this process, a collaboration for which NCIPC is very grateful. In June 2018, NCIPC requested formation of a multidisciplinary Opioid Prescribing Estimates Workgroup (OPE WG) to help inform this project. From September through October 2018, the OPE WG met via teleconference four times to discuss project approach. In December 2018, the OPE WG Chair presented the WG's findings to the NCIPC BSC, who provided recommendations to NCIPC on the direction of the project based on review of the OPE WG report.

In terms of the study methods, this was a retrospective cross-sectional analysis of administrative claims data from[1] two different data sources. One was OptumLabs Data Warehouse (OLDW), which is a nationally representative sample of patients with commercial insurance and Medicare Advantage, referred to throughout this presentation as "those with private insurance." The study period for this cohort was January 1, 2017 to December 31, 2017. The second was the MarketScan® Multi-State Medicaid Database, which contains all Medicaid beneficiaries in 9 anonymized states distributed across census regions. The study period for this dataset was October 1, 2016 to September 30, 2017. The slight difference between the two study periods was simply a reflection of the access available to each dataset at the time of the analysis.

Over 40 indications associated with pain were included in the study, such as indications associated with non-surgical acute pain (renal colic, low back pain); chronic pain (e.g., back pain, fibromyalgia); post-surgical pain (e.g., laparoscopic and open procedures); and pain related to sickle cell disease and active cancer, which was analyzed separately from the categories already mentioned. Linkage algorithms were developed to link patients' opioid prescriptions to medical encounters using patient identification (ID), visit and prescription dispensing dates, clinician ID, and index diagnosis of the condition that was linked to pain. Then prescribing rate by indication and by age, days of opioids supplied, and daily dosage in morphine milligram equivalents (MME) were calculated per prescription. The following table shows the full list of the non-surgical acute, chronic, and post-surgical procedures included in the study:

Non-Surgical Acute Pain Conditions • Abdominal pain • Acute low back pain • Acute migraine • Dental pain • Herpes zoster • Musculoskeletal sprains and strains • Renal colic • Rib fractures **Chronic Pain Conditions** • Chronic radicular or nonradicular back pain • Chronic neck pain • Fibromyalgia • Inflammatory joint disorders • Irritable bowel syndrome • Non-migraine headaches • Osteoarthritis or joint cartilage conditions • Periarticular or soft tissue disorders	**Post-Surgical Pain Conditions** • Total hip arthroplasty • Open cholecystectomy • Cesarean section • Spinal fusion • Lumbar decompression • Simple mastectomy • Laparoscopic appendectomy • Open inguinal hernia repair • Coronary artery bypass • Tonsillectomy • Laparoscopic colectomy • Parathyroid/thyroid surgery • Total knee arthroplasty • Laparoscopic cholecystectomy • Vaginal delivery • Combined spinal fusion/lumbar decompression • Excisional biopsy • Lumpectomy/partial mastectomy • Laparoscopic abdominal solid organ resection • Laparoscopic inguinal hernia repair • Arthroscopic rotator cuff repair • Arthroscopic knee surgery • Open colectomy • Sinus surgery

Overall, over 18 million patients with private insurance were included in the datasets during the study period. Of those, 50.3% were female with a mean age of 42.7 years, 35.4% had one or more visits with ≥1 pain-related diagnosis/surgical procedures, and 35.6% of that group had at least 1 opioid prescription identified. Over 11 million patients were identified with Medicaid in this dataset during the study period. Among them, 56.1% were female with a mean age of 20.4 years, 27.7% had one or more visits with ≥1 pain-related diagnosis/surgical procedures, and 35.5% of this group had at least 1 opioid prescription identified.

In terms of key findings for non-surgical acute pain conditions, just over 2 million visits with private insurance benefits and over 1.6 million visits were linked to Medicaid benefits. Opioid prescribing rates ranged from 4.6% for acute migraines to 44.8% for rib fractures for private insurance, and 6.6% for acute migraines to 56.3% for rib fractures for Medicaid. The mean days' supply for private insurance ranged from 4.1 for dental pain to 12.6 for acute migraine, and 4.0 for dental pain to 9.9 for acute migraine and acute low back pain for Medicaid. The mean daily dosage per prescription was consistently about 30 MME per day for all non-surgical acute pain conditions across both datasets.

For chronic pain, just under 1.5 million patients with private insurance and about 500,000 patients with Medicaid benefits were identified. Back pain was the most common chronic pain indication in both datasets and was linked to 49.3% privately insured and 52.2% Medicaid enrollees, with any chronic pain condition included in the study. Over >30% of privately insured and almost 50% of Medicaid patients had at least 1 opioid prescription linked to their chronic pain condition. The study found that 12.6% of private insurance patients and 20.0% of Medicaid patients with chronic pain received long-term opioid therapy (LTOT) for that condition. The most common chronic pain condition for which LTOT was continued was chronic non-radicular back pain. About 90% of patients with both insurance types who had this chronic condition were continued on long-term opioids. The mean daily dosage issued to patients with chronic pain exceeded 50 MME per day for nearly all privately insured patients, although that pattern did not hold for Medicaid patients for whom the mean daily dosage was less than 50 MME per day.

About 87% of private insurance patients and 80.0% of Medicaid patients with chronic pain were not receiving LTOT. For this group, opioid prescribing rates ranged from 6.5% for irritable bowel syndrome (IBS) to 28.3% for chronic radicular back pain for patients with private insurance and 13.4% for IBS to 44.0% chronic radicular back pain patients with Medicaid. The mean daily dosage issued to patients with chronic pain not receiving LTOT was consistently about 30 MME per day across both datasets.

Turning to post-surgical pain, just under 400,000 surgical procedures among those with private insurance and almost 300,000 procedures associated with Medicaid were identified. Of the surgical procedures associated with private insurance, 66% were linked to opioid prescriptions. Among those with Medicaid, 55% were linked to opioid prescriptions. On a procedure-specific basis, among patients not already on LTOT, opioid prescribing rates ranged from 23.6% for vaginal delivery to 93% for arthroscopic rotator cuff repair among private insurance patients and 30.7% to 94.4% for the same procedures among Medicaid patients. The mean days' supply of opioids among patients not on LTOT was 4.1 for vaginal delivery to 9.5 for spinal fusion/decompression among private insurance patients and 4.2 to 9.1 among Medicaid patients for the same procedures. The mean daily dosage in MME per day among patients not already on LTOT was 37.4 (lumpectomy/partial mastectomy) to 63.5 (combined spinal fusion/decompression) for private insurance patients and 27.3 (tonsillectomy) to 62.9 (combined spinal fusion/decompression) for Medicaid patients. Patients already on LTOT nearly always received opioids at discharge and the mean days' supply and daily dosage was nearly always higher than for those patients who were not already on LTOT prior to surgery.

The study found that almost half of all patients with sickle cell disease (SCD) received opioids 42.6% for those with private insurance and 44.9% for those with Medicaid. However, there were some differences in prescribing by age. For example, 29.0% of children 18 years of age and younger with Medicaid benefits received opioids; whereas, only 12.2% of children with private insurance did. Among non-elderly adults defined here as those 19-64 years of age, Medicaid patients received 117.3 days' supply versus 59.2 days' supply among privately insured patients. There are a few limitations to note about the analysis of opioid prescribing for SCD. It was not possible to differentiate between an acute vasoocclusive crisis and chronic SCD pain using claims data, and the small number of privately insured patients with SCD may not represent the general SCD population. Thus, there are a few caveats to the interpretation of the results, particularly among the privately insured.

Among those patients with active cancer, differences were found in opioid prescribing by insurance type. In summary, patients with Medicaid benefits received opioids more frequently, a larger days' supply, and a higher daily dosage.

Variations in opioid prescribing by age were identified in these analyses. Compared to adults, children 18 years of age and younger received shorter prescription durations for most indications; lower dosages for SCD, post-surgical pain, and cancer; similar dosages for non-surgical acute pain; and fewer prescriptions for chronic pain specifically among patients with Medicaid. Compared to non-elderly adults (19-64 years), elderly adults (aged 65 years+) received fewer prescriptions for dental pain, renal colic, most surgeries, and cancer; and lower mean dosages for LTOT after surgery or for SCD or cancer.

These results are notable because in some instances, they do not align with evidence-based published guidance. For example, non-opioid treatment is recommended for the following conditions on this slide (fibromyalgia, chronic and acute low back pain, musculoskeletal

sprains/strains, and dental pain), but opioid prescriptions were found to be issued to patients in this study. For fibromyalgia[2,3], the study found that 23.5% of privately insured and 31.1% of Medicaid patients not already receiving LTOT were newly prescribed at least one full month's supply of opioids. Among patients with chronic[2,4,5] and acute back pain[2,4,5], 28% of privately insured and 44.0% of Medicaid patients not already on LTOT were started on opioids. Among visits linked to acute back pain, 11.8 days of opioids were supplied for privately insured patients and 9.9 days were supplied for Medicaid patients. A sizeable proportion of patients with musculoskeletal strains or sprains[6] (12.9% privately insured and 14.8% Medicaid) or dental pain[7,8] (27.2% privately insured and 11.8% Medicaid) were prescribed opioids.

To highlight a few other comparisons to published guidance, for many patients with chronic pain conditions receiving LTOT, daily dosages were greater than 50 MME per day—a threshold above which adverse events (AEs) are increased[9]. The study found that post-operative opioid prescribing exceeds many published recommendations. One-third of privately insured and about half of Medicaid enrollees with cancer received opioids, despite opioids being recommended in published guidance for pain associated with cancer[10]. Fewer than half of all patients with SCD across the entire study were prescribed opioids, despite reports of suboptimal management of SCD-related pain.

In conclusion, opioid prescribing patterns for some indications were incongruent with existing evidence-based guidelines. This may reflect low clinician awareness of guidelines or perhaps reluctance to adhere to guidance. Implementation guidance that emphasizes evidence-based recommendations has the potential to better align opioid prescribing with evidence on benefits, thus improving pain management and patient safety. The studies and guidelines referenced throughout the presentation are as follows:

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Acute Pain Treatment Resources

LeShaundra Cordier, MPH, CHES
Associate Director of Communications
Division of Overdose Prevention
National Center for Injury Prevention and Control
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Ms. Cordier provided an update on some of the resources that are being developed to support the CDC Opioid Prescribing Estimates Project work, showcasing some of the tools and resources to help providers treating common acute pain including the website, training modules, videos, and fact sheets. These materials are translations of existing clinical guideline recommendations and are being designed with providers in mind in terms of how to help them implement best prescribing practices.

The Acute Pain Website highlights the current treatment recommendations from professional organizations and gives background information for selected common acute pain conditions (e.g., acute migraines, ankle sprains, dental pain, acute low back pain, and post-surgical pain). The website has the recommendation statements and materials posted on it. It is intended to serve as a reference for providers based on external research and interesting published guidelines. The content on the website represents the current best practices and is not considered to be CDC-authored or CDC-endorsed content unless expressly stated. The information provided on the website is not intended to be a substitute for medical judgment of the clinician, but instead is to help provide data relevant to physicians, references, and additional resources that can help providers in what they are doing. The website launched this year and continues to expand as more resources are developed. Eventually it will house some of the additional tools such as training modules, videos, and fact sheets. It is being updated with interactivity, responsiveness, and animation. The enhanced functionality will allow providers the ability to easily scroll through content no matter what device they are using, and to help them better navigate the site and tools as needed.

CDC has two interactive training modules that are currently in development, which are anticipated to be completed soon. The first module is “Treating Acute Pain Safely and Effectively.” This module will present evidence-based strategies for treating common acute pain conditions, including some of the ones featured on the website. The second module is “Treatment of Acute Postsurgical Pain.” This module is intended to increase awareness of treatment strategies in this setting. Both of the modules provide an overview of published clinical guidance, patient scenarios, and resources. Providers will be able to earn continuing education (CE) or continuing medical education (CME) credits by completing the modules. The modules are anticipated to be released in Fall 2020.

Three videos are currently in production that will deliver key points about safe and effective treatment for dental pain, ankle sprains, and low back pain. These are brief animated videos with visuals representing primary learning points. Fact sheets are also being developed that are intended to be a quick reference for providers, which also will include additional resources. The fact sheets will translate some of the recommendations. The first group of fact sheets will focus on the management of acute low back, ankle sprains, acute migraines, and post-surgical pain.

The videos and fact sheets will be posted to the website and shared as part of the training and other materials being developed.

Discussion Points

Dr. Floyd asked whether they could discern from the data any impact of an intervention such as physician monitoring programs on the prescribing rates.

Dr. Mikosz replied that the analysis was not set up to evaluate that. They were looking purely at administrative claims data, so they were not able to assess the impact of Prescription Drug Monitoring Program (PDMPs).

Dr. Coffin thought there was a very strong outcome from the work that was done. Based on the paper, he was curious about the reason for the difference between private insurance and Medicaid. He thought perhaps some things that might contribute to the difference would be structural barriers to avoiding LTOT, including the need to be actively treated for a disease to access disability, additional co-morbidities that patients with Medicaid may suffer from, limited resources such as not having a car to drive to physical therapy appointment, et cetera.

Dr. Mikosz said they had similar questions as they were going through this analysis. The way they were able to access the datasets precluded any more detailed comparisons head-to-head between these two datasets to help tease out some of the issues that Dr. Coffin raised. They mentioned in the paper the different drug utilization strategies that Medicaid has in place compared with commercial payers, such as prior authorization that may affect use of opioid medications and other non-opioid medications that could be playing a role. Barriers to accessing care also could be impacting the outcomes. There was a big age difference between the two datasets as well that could have impacted the results. These are good issues to raise and possibly explore further in other analyses.

Dr. Liller asked whether there are any plans to follow up this quantitative study with any qualitative studies among providers to find out more information, such as through interviews and/or focus groups, to expand upon what the quantitative data showed.

Dr. Mikosz thought this would be interesting to consider. There are no set plans to do this as another arm of this particular study, although the next presentation in this meeting would be by CDR Kinzie Lee who would talk about stakeholder engagement that would touch on this somewhat.

Dr. Kaplan asked whether they found in difference in states that had adopted Medicaid Expansion versus states that did not.

Dr. Mikosz agreed that some of the other factors that could have played a role in opioid prescribing rates are important to think about, but they did not have access to that information in their datasets. Although the MarketScan® Multi-State Medicaid Database contained all Medicaid beneficiaries in 9 states, the states were anonymized so they were not able to assess specific states.

Dr. Compton noted that one of the major issues has been with leftover medications. He was intrigued by the fairly small number of days of supplies seen in multiple clinical studies. Even with a decreasing duration of days, people still seem to take a small portion of the pills that are

dispensed. While he understood that the investigators did not have data on consumption, he wondered whether there was any information on the number of times that refills were required. Ostensibly at some point as the number of days supplied are reduced, some people will find it inadequate and will request refills.

Dr. Mikosz indicated that they do not have information on refills. When assessing the prescriptions that were issued, particularly for acute pain and following surgery, it was the prescription that was issued at discharge after surgery and for the specific encounter for acute pain. While they did not have any information on refills, she acknowledged that it is important to explore at a future date.

Regarding the education materials, **Dr. Porucznik** wondered whether there are parallel efforts with medical schools and/or residency programs in order to train the next generation of providers.

Ms. Cordier indicated that they have been working with medical schools and others to help develop some of the training products that they have created to ensure that they are useful and can be implemented in those spaces. While she would not call it a "parallel effort," they are working with medical schools and others to help develop content so the resources can be promoted further with students.

Dr. Mikosz emphasized the importance of making sure that the next generation of clinicians who are coming up in training have a good understanding of best practices for pain management and clearly understand the nuances of treating pain in general. It is a difficult condition to treat, so it is important to ensure that there is abundant education related to the individualized decisions for each patient that need to be taken into account when treating pain and that there is no "one-size-fits-all" approach. There has been some energy among organizations such as the Association of American Medical Colleges (AAMC) in working on this. They held a convening last year that was well-attended by many medical training programs, bringing together a lot of people into one room to brainstorm about strategies that have worked among medical educators.

Ms. Cordier added that they have been evaluating the existing training modules that CDC already created and recognized that some of the biggest university systems are tracking use, so the agency is working with them to ensure that the modules are beta tested and that other areas necessary for CE are addressed.

Dr. Chou asked about whether race and ethnicity were considered as factors in terms of variability in prescribing patterns, which could be informative as well. The conclusion was suggested that perhaps cancer pain is being under-treated, but there is such variability in cancer pain among individuals that it is difficult to interpret what it means that 20% to 30% of people with cancer pain receive an opioid. Similarly with dental pain, there are some indications where it is pretty clear that opioids are not indicated. For example, wisdom tooth extraction differs from a major dental surgical procedure. He wondered whether consideration had been given to performing follow-up analyses to dive further into those data.

Dr. Mikosz indicated that they did not have race and ethnicity data for this particular study, but those are of keen importance to them. As Dr. Houry mentioned, NCIPC wants to make sure that they have very focused attention on assessing racial and ethnic disparities in care, particularly for pain management. They are giving thought to how to incorporate that in any follow-up

analyses to this project. Regarding interpretation of cancer and dental pain, they are still trying to determine the landscape of what any follow-up analyses would look like. While she did not include dedicated information in her presentation about all of the study limitations, there are others such as the use of claims data, its analytic limitations and the conclusions that can be drawn from that. They were just providing a snapshot of trends for an array of conditions associated with pain to use as a jumping off point for further discussion for clinicians and health systems to think about how prescribing practices might compare and how it compares qualitatively against other published evidence-based guidelines. There are some nuances lost, given that this type of analysis cannot capture the reasons patients do or do not receive opioid prescriptions. It is a population level study, so it is not possible to capture the nuances that come with treating pain among individual patients. She recognized the importance of all of the points raised and they will think further about next steps for this study.

Dr. Cunningham reiterated the importance of measuring race, ethnicity, and structural racism in order to make the necessary corrections to address these.

Dr. Mikosz stressed that this is on NCIPC's radar and is of high interest to them.

Management of Acute and Chronic Pain
Opportunities for Stakeholder Engagement and Public Comment

Kinzie Lee, MPH
CDR, US Public Health Service
Lead, Strategic Partnership Team
Office of Policy and Partnerships
National Center for Injury Prevention and Control
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CDR Lee recalled that back in August of 2019 everyone was still going to conferences, attending trainings, and stopping by people's offices. Months before COVID-19 was coined as the term being used for the current pandemic, NCIPC began considering what an expansion to the guideline would look like and how they might think about engaging stakeholders in a different way. The plan that was developed in December 2019 included public comments, robust in-person and group conversations and activities, and work in 5 communities across the US. By February 2020, that plan changed quite dramatically. The planned in-person conversations were changed to phone conversations, which was to protect those with whom they were talking as well as themselves from what continues to be an ever-changing pandemic. CDR Lee reviewed the current plan, provided a few high-level themes that have been identified through the public comment period they were able to do, and described next steps.

In seeking to understand more about pain and pain management, NCIPC is adopting a comprehensive approach by tapping into the quality of evidence; balance of benefits and harms; and the lived experiences, values, preferences, and perspectives of the stakeholders the Injury Center serves. Each of these offer a wealth of information that can inform the work we do around pain, including the update of CDC's *Guideline for Prescribing Opioids for Chronic Pain.*

To gain stakeholder perspectives, CDC is undertaking a two-pronged, non-research process. The first path was to solicit written public comment through the *Federal Register*. That notice was called "Management of Acute and Chronic Pain: Request for Comment" and was published on April 17, 2020 and closed on June 16, 2020. The second path is to have individual conversations over the phone or through an internet-enabled virtual platform. The opportunity to

participate in these engagements will be announced through a companion *Federal Register Notice* (*FRN*) called "Management of Acute and Chronic Pain: Opportunity for Stakeholder Engagement," which was published July 22, 2020 and would be open for the next 30 days. The stakeholders being engaged include patients with acute or chronic pain, patients' family members and/or caregivers, and healthcare providers (HCPs) who care for patients with pain or conditions that can complicate pain management like opioid use disorder (OUD) or overdose. Through the public comments and stakeholder conversations, CDC will gain insight about stakeholders' experiences in how they manage pain and the benefits, risks, and/or harms in terms of different types of pain management options (e.g., non-opioid pain medications or non-pharmacological treatments like exercise therapy or cognitive behavioral therapy). They also want to know how people are choosing between all of the different pain management options, including how they consider factors such as the cost of the option, whether it is accessible, and the benefits/risks of that option. Also of interest is understanding where people find information when they need to make pain management decisions.

The inferences gained from patients, caregivers, advocacy/industry groups, and HCP will be combined with the public comments received from the *Federal Register* and analyzed for themes that will be shared with the authors who are writing the first draft of the updated or expanded guideline. This is to help the authors understand stakeholder values and preferences. It also is anticipated that the themes and insights can be used as inspiration for NCIPC as they think about how to design potential dissemination and engagement strategies once the guideline is released.

NCIPC is beginning to more thoroughly analyze the public comments received through the *FRN* that closed on June 15, 2020. CDR Lee provided a glimpse into what they are seeing so far. The comment period remained open for 60 days and received, on average, more than 88 comments per day, resulting in 5297 total comments. Of those, 4085 (77%) were from patients, 416 (13%) from caregivers, 698 (8%) from advocacy/industry groups, and 101 (2%) from providers. While the fewest comments received were from individual providers, quite a few organizational comments were received that focused on some of the provider issues. CDR Lee emphasized that they have just begun to analyze these, so it is possible that they might shift somewhat. As they have more time to work with the information, additional areas are likely to arise.

Within the large patient stakeholder group of 4085 comments, respondents commented on their own experience needing, seeking, or receiving pain management options. These patients reported frustrations in accessing or receiving opioid medication as a result of the 2016 Guideline; experiences using non-pharmacological pain management options; and insights comparing chronic pain management before and after the 2016 Guideline. Respondents commenting on their experience providing mental, emotional, or physical support to a friend or family member who requires pain management (N=416) reported experiences providing support to family members or friends who manage acute or chronic pain, perspectives around others' increased quality of life as a result of taking pain medication(s), and impact of the 2016 Guideline on their family member's or friend's access to pain medications.

Respondents commenting on their experience providing pain management options (N=101) reported opinions around the need for additional guidance within the 2016 Guideline, frustration with the lack of autonomy with their patients, and recommendations for non-opioid substances and treatments for pain management. Respondents commenting as an affiliate with an organization or as a pain management advocate who did not provide identifiable information (N=698) reported impacts of the 2016 Guideline on patients and providers such as untreated

pain and fear to prescribe, support for a multi-disciplinary approach to pain management, and recommendations for training programs for prescribing doctors and pain management options. NCIPC did not specifically request input from the advocacy/industry stakeholder group, many comments were received from these stakeholders. Most (38%) of them were from advocacy organizations, followed by organizations that provide direct medical service and medical professional organizations.
As noted earlier, the second *FRN* was published the same day as this meeting to solicit volunteers to participate in the second component of the stakeholder engagement in order to deepen the understanding of perspectives on and experiences with pain and pain management, including but not limited to the benefits and harms of opioid use. In early fall, CDC will be holding approximately 100 individual conversations with stakeholders over the phone or through an internet-enabled virtual platform. These conversations will be about an hour each and are intended to supplement what they heard from stakeholders during the public comment period and allow them to add more context to what they heard from patients, caregivers, and providers. During those conversations, the project team will invite input specifically focused on using or prescribing opioid pain medications, non-opioid medications, or non-pharmacological treatments (e.g., exercise therapy or cognitive behavioral therapy). Again, the insights gathered from patients, family members/caregivers, and health care providers will be combined with public comments from the *Federal Register* and analyzed for themes. These themes will be shared with the authors who are drafting the Guideline update to further inform their work to understand stakeholders' values and preferences. The themes also will be used to inform the design of potential dissemination and engagement strategies for the planned Guideline update.

Looking ahead, CDC highly values stakeholder and public engagement and will continue to notify the public of all future opportunities for public comment. As mentioned, they anticipate that the companion *FRN*, *Management of Acute and Chronic Pain: Opportunity for Stakeholder Engagement,* posted earlier in the morning and will be open for 30 days. Those interested in receiving information related to the ongoing work of NCIPC, especially that specific to drug overdose prevention, were invited to sign up at www.cdc.gov/emailupdates and select topics of interest. Subscription Topics include: Injury, Violence, and Safety and the Subtopic is Drug Overdose News.

To gain insights and ideas from the BSC, CDR Lee posed the following questions for consideration during the discussion period:

- ❑ How might we encourage practicing HCP to participate, given competing priorities of the COVID-19 response and clinical duties?

- ❑ How might we acknowledge potential feedback about COVID-19, while still focusing the conversations on information that can inform the guideline update?

- ❑ How might we select 100 individuals for the non-standardized conversations in the most equitable and non-biased way possible?

- ❑ How might we address other areas of insight learned through observations, is there a role for the BSC?

Discussion Points

Dr. Liller noted that this presentation addressed some of the questions she posed earlier about qualitative work. She asked whether they have an interview guide that will be used with the 100

respondents, and if they will be asking questions that will delve further into the findings from the quantitative study. There are some questions that came out in the quantitative survey that they may be able to ask more about.

CDR Lee indicated that they are working with the Office of Personnel Management (OPM), which is running these as conversations. This essentially means that they have a conversation guide. None of the participants will be asked the same questions. The beauty of this type of engagement is that it allows for personal connection and empathy-building to dig deeper into why people choose what they do. She has seen in the past that oftentimes what they hear will inform various questions, but they do go into the conversations without a preconceived idea of how the conversations might occur. There are many questions that would be interesting to dig into further, which offer opportunities to look more deeply in thinking through potentially how to design future opportunities to engage people.

As a practicing clinician from Upstate New York and a member of the Opioid WG, **Dr. Floyd** said he certainly has ideas about how to engage clinicians. In terms of why people still are not following guidelines, the critical reality at the grassroots clinical level is that HCP are seeing patients who present in pain sometimes at the point of being in tears. HCP are grappling with how to deal with such situations and to be honest, the guideline is not foremost in mind when dealing with an acute and critical situation such as that. In addition to getting the guideline out, it is important to monitor what is occurring at the grassroots level. In monitoring individual clinicians prescribing within their local healthcare system, they are seeing a wide range of clinicians who are over-prescribing. In going through these analyses, he asked how the NCIPC project group is looking at what individual healthcare systems are doing to monitor clinicians' prescribing habits and to work with them locally with the guideline that have been established. That seems to him to be key in terms of bringing the guideline to the grassroots level and to implement and monitor them in order to have an impact on this crisis.

CDR Lee indicated that one of the things they are interested in through the stakeholder engagement is seeking practicing physicians in the field to learn from their perspective what is working, what they are struggling with, and how NCIPC can server them better. Through some of those very deep and specific practicing provider questions, they hope to scrape the surface of some of that. That is a great area to look at in the future.

Dr. Schwebel offered a different perspective as a psychologist who is not involved at all in prescribing. To him, a lot of what they were hearing from all of the presenters related to the challenges of human behavior. A key piece is thinking through the goals, motivations, and reasons for prescribing and the dynamic relationship with the patient. That is an individual, case-by-case issue. These interviews may help to unpack that very complex dynamic relationship. Then there are the goals, motivations, and influences of the insurance and pharmaceutical industries. It all becomes highly complex. He liked what he had been hearing and thinks it will help them discover what is causing the public health problems. Some of his thoughts on the specific discussion questions were on: Question 1) To encourage practicing HCP to participate, offer fair and appropriate financial reimbursement for their time at a rate appealing to providers and schedule conversations at convenient times; Question 2) COVID-19 is important, but this is too. He would just re-direct to the opioid topic if they veer off course; and Question 3) Is an important question. Maybe consult with an appropriate biostatistician who can help with a randomized selection plan.

CDR Lee said that as one of the individuals who was responsible for reading many of the over 5000 comments received, the issue of complexity was very clear out at all levels. They hope to gain further insight through these conversations.

Dr. Coffin observed that there are ways to address COVID-19 without derailing the conversation that COVID-19 has obviously changed practice, including around controlled substances, due to regulatory changes from the federal government that have liberalized somewhat the prescribing of controlled substances. Given the urgency of COVID-19, he suspects that a lot of providers have put tapering on hold. It would not be surprised if there is some divergence in the 2020 prescribing data that is associated with COVID-19. It might be interesting to explore that proactively to examine how providers and patients feel about the changes that have been wrought by COVID-19 in terms of controlled substance access, opioid measures, how changes have influenced practice, and the pros and cons that they see in the shift to telehealth and away from the more intensive care that is usually associated with controlled substance prescribing.

CDR Lee agreed that this would add one more layer onto the things they could explore. The telehealth component and expansion of that would be interesting to know more about it.

Dr. Frye supported Dr. Liller's suggestion to link the quantitative analyses and conversations to one another. This presents a tremendous opportunity to dive more deeply into the findings. Circling back to Dr. Cunningham's point, she agreed with the importance of conducting these conversations through an equity lens by asking questions about the role of race and racism and class and classism. These are areas that need to be discussed frankly with stakeholders, and that would lend some depth and nuance to the conversations as well.

CDR Lee agreed that including those specific topics in future work would be amazing. She noted that all of the BSC members are on their distribution list and that the plan is to send an official announcement to solicit volunteers. She encouraged the members to consider putting their own names forward and to share the invitation widely with their colleagues to potentially participate in these conversations.

Dr. Greenspan added that if BSC members and *ex officios* have comments who did not have a chance to articulate them, they could add them to the Chat Box to be provided to the speakers for this and other presentations.

Update: BSC/NCIPC Opioid Workgroup Formation

Melanie Ross, MPH, MCHES
CDR, US Public Health Service

Deputy Branch Chief, Health Systems and Research Branch
Division of Overdose Prevention
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

CDR Ross reminded everyone that in December 2019 during the last NCIPC BSC meeting, CDC requested the establishment of a WG that would inform a possible update or expansion to the *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*. During this session, she provided an update on those formation activities. She thanked the BSC members for their thoughtful feedback regarding the development of the OWG. CDC incorporated the

feedback received, including geographic diversity, diversity in clinical and patient perspectives, and maintaining breadth by identifying potential OWG members who had more than one specialty. CDR Ross indicated that she would review the purpose and charge of the OWG, discuss the nomination process, announce the roster of members, and highlight future plans. The purpose of the OWG is to: 1) review a draft, updated and/or expanded *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016* and to develop a report that will provide the OWG's findings and observations about the draft Guideline to the NCIPC BSC parent committee; and 2) on request, provide expert input and observations on other matters related to the opioid crisis.

The OWG will provide observations on the draft 2022 Opioid Prescribing Guideline by completing the following tasks, which are to:

- ❑ Review the quality and implications of clinical and contextual evidence reviews.
- ❑ Review each guideline recommendation statement and accompanying rationale.
- ❑ Consider specific aspects of each recommendation:
    - ➢ Quality of the evidence supporting the recommendation, assessing the accuracy of the evidence quality rating (i.e., evidence "type")
    - ➢ Balance of benefits and risks associated with the recommendation (including the degree to which the benefits of issuing the recommendation can be anticipated to outweigh the harms)
    - ➢ Values and preferences of clinicians and patients related to the recommendation (including the degree to which there is variability or uncertainty in values and preferences)
    - ➢ Cost feasibility of the recommendation (including the degree to which implementation is anticipated to be feasible for health systems and patients financially); and
    - ➢ Category designation of the recommendation (whether Category A or Category B is justified):
        - Category A recommendations apply to all patients.
        - Category B recommendations require individual decision making where different choices will be appropriate for different patients so that clinicians must help patients arrive at a decision consistent with patient values and preferences and specific clinical situations.
- ❑ Develop a summary report, including points of agreement and disagreement, of the workgroup's observations associated with items listed above for the draft updated/expanded 2022 Guideline. This summary report will be disseminated and discussed at an NCIPC BSC meeting in the future prior to the publication of the 2022 Guideline.

Following approval by the NCIPC BSC to create the OWG, the nomination process opened December 4, 2019. The nomination period was open for 2 months and closed on February 4, 2020. CDC received 255 nominations indicated by submission of a curricula vitae (CV) by the nomination deadline. CDC reviewed CVs and developed a list of prospective OWG members to

provide a balance of perspectives that would enhance and support the OWG's capacity to complete tasks, engage audiences directly affected by the Guideline, engage audiences who would be directly involved in implementing or integrating recommendations into current practices, and engage audiences qualified to provide representation of a specific discipline or expertise in alignment with the tasks of the OWG. They sought to represent a wide range of clinical specialists who may engage in treating persons living with acute or chronic pain, such as dentists, primary care clinicians, surgeons, and other clinical specialists such as addiction medicine, anesthesiology, emergency medicine, and medical toxicology.

In accordance with the Terms of Reference, the OWG will be comprised of 12 to 25 members. The OWG Chair must be an appointed NCIPC BSC member and there must be at least one other OWG member who is an appointed member of the NCIPC BSC. Remaining memberships will be comprised of external members. The OWG also must have a CDC employee as a Designated Federal Official (DFO). All prospective OWG members received a letter of invitation and COI disclosure form to complete. In the final step of forming the OWG, CDC submitted the prospective OWG roster, CVs, COI forms, and Terms of Reference to CDC's Strategic Business Initiative Unit (SBI) that provides oversight of the FACA committee management and CDC's Ethics Office. All COI forms were reviewed and none of the disclosed interests by the prospective OWG members represent a COI at the present time in accordance with applicable laws and regulations. The final Terms of Reference and OWG Roster were provided to the NCIPC BSC with the materials for this meeting. CDR Ross read the OWG members in alphabetical order.

CDR Ross thanked everyone who expressed interest in serving on the OWG. CDC values engagement from the public and the various areas of expertise that they bring and hopes that everyone will take advantage of opportunities to state engaged in this process. Some of those opportunities include the Stakeholder Individual Conversations announced earlier in the morning through the *FRN*, "Management of Acute and Chronic Pain Opportunity for Stakeholder Engagement." Also, written public comment for the July 22, 2020 NCIPC BSC meeting is open through July 28, 2020. Oral and written public comments for any future NCIPC BSC meeting will be announced through the *FRN*, and the public comment *FRN* once the Guideline update is drafted. This is anticipated in late 2021.

Discussion Points

Dr. Liller asked whether this guideline would be an expansion of the Chronic Pain Guideline and if the Acute Guideline would be included.

Dr. Dowell clarified that this is intended to be an update of the CDC *Guideline for Prescribing Opioids for Chronic Pain—United States, 2016* with a potential expansion into acute pain. NCIPC is still going through the comments received, but there were many requests from professional organizations and health professionals to include guidance on acute pain and they are aware of previous requests for CDC to expand the Guideline to include acute pain. Given that, they asked AHRQ to undertake a systematic review of the evidence on opioids and other treatments for acute pain and consideration is being given to including acute pain in the update.

Dr. Frye asked whether CDC is confident that prospective patients, family members, and caregivers are adequately represented in this group.

CDR Ross replied that she is comfortable with the perspectives and clinical specialties that are represented on the OWG. They do have representatives of people who deal with chronic or

acute pain, as well as family members. Those were not called out in the list but were disclosed during the nomination process in their CVs or via email. The OWG has been finalized per approval from the CDC SBI Unit. The final Terms of Reference and OWG Roster were approved. All COI forms were reviewed, and no conflicts were identified at this time. Therefore, the OWG Roster is final at this time.

Public Comment Session

Overview

Victoria Frye, DrPh, MPH
Chairperson, NCIPC BSC
Associate Medical Professor
Department of Community Health and Social Medicine
City University of New York School of Medicine
City College of New York

Dr. Frye expressed appreciation for those who took the time to participate in this meeting. She noted that all written comments would be posted on the BSC website with the finalized meeting minutes. As described in the *FRN* announcing this meeting, the public was requested to pre-register if they wanted to provide comments. This was done on a first-come first-served basis. Given the number of requests to make public comments, she requested that everyone keep their comments to no more than 2 minutes in order to hear from as many people as possible. Comments would be heard from those who pre-registered and others would be offered the opportunity to comment if there was time remaining. In the event that the allotted time were to run out before all comments were made, commenters were invited to submit public comments in writing to ncipcbsc@cdc.gov. She indicated that written public comments would be accepted through July 28, 2020 at 5:00 PM. There will be additional upcoming opportunities to comment. She introduced Victor Cabada, who would be working with the operator to facilitate the public comments.

Victor Cabada, MPH
Office of Science
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Mr. Cabada thanked everyone for time to comment and indicated that he would call on commenters in the order in which they pre-registered. He reminded everyone that there would be a 2-minute time limit. He also indicated that they would not address questions during this session, but any questions posed by members of the public would be considered by BSC and CDC in the same manner as all other comments. He instructed anyone with the media to direct their questions to CDC's Media Relations Office.

Public Comments

Rose Bigham
Chronic Pain Patient & Advocate
Washington, DC

I am a chronic pain patient and advocate in Washington State and I Co-Chair the Washington Patients in Intractable Pain. I just want to say quickly that I'm a little bit shocked at the omission

of any patients on the Opioid Workgroup roster after hearing since December that patient voices were considered important in the diversity and perspective. Yet, here we are again with zero patient voices despite our community being the most significantly impacted by the 2016 Guideline and its potential revision. My other comments are two things. One, you need to track patient outcomes. Creating new policy about prescription opioids without creating comprehensive measures and reporting patient outcomes makes it abundantly clear that the goal is not better patient outcomes, but just lower prescribing numbers. Put simply, no one is tracking what has happened to the millions of people nationwide who have been stable on prescription opioids for managing their pain for many years but now find themselves denied effective pain relief due to policies from hospitals, clinics, pharmacies, or providers who have become too afraid of retaliatory oversight to effectively treat their patients in pain. Second, measuring prescriptively without context is unethical. Measuring the effectiveness of prescription opioid policies solely on the number of prescriptions written or the average MME dose without any context of those patients and their medical diagnoses and whether they are better off now with fewer prescription opioids or are, in fact, worse is not only misguided, it is unethical. Celebrating victory because of fewer and lower prescriptions without having any idea if the patient outcomes are better or worse is irresponsible and leads to deadly consequences. Chronic pain patients who are suffering in untreated agony are choosing suicide or trying to find new and dangerous ways to manage their pain outside of the medical system which has failed them, and have experienced traumatic losses in quality of life, relationships, and financial stability due to inability to work. Moving forward, please ensure patient representation and an unbiased look at the science-based evidence. Millions of Americans in pain are relying on ethical and unbiased review of the evidence and having medically appropriate access to pain relief with individualized care. Transparency in patient outcomes is key to gauging the effectiveness of any opioid prescribing guidelines. Thank you.

Dr. Nita Klein?
Director of Research
Heads Up Migraine

I am Dr. Nita Klein? I am the Director of Research at Heads Up Migraine. We are a patient volunteer organization dedicated to improving access to care for patients. I will echo Rose's statement that I am shocked at the lack of patient representation. I would like to just make one point today. There is a constellation of medical and non-medical users and a constellation of lessening prescription with illicit opioids has resulted in policies that have been disastrous to patients of chronic progressive diseases, and it does not look like there is any change. There has been very little done since the CDC 2016 Guideline has been grossly misinterpreted. This was an entirely foreseeable result. Once the CDC puts those numbers of opioid prescriptions, it was almost inevitable that legislators would seize on them as a metric in the prosecution of the war on drugs. Except this time, the target was pain patients and physicians. And what did we see? The results of rapid reduction [someone on Adobe Connect is talking over her and was requested to mute, but she did not repeat, so some of what she said is missing] in previous stable patients with intractable pain. We have had a lot of recent research that shows that this has increased the risk of death substantially. The sole metric that CDC and other researchers use is decline in prescriptions. The metric should be patient outcome. The version that is used has created a new problem—the increased instability and lack of access to care for seriously ill Americans without addressing the problem it is supposed to address. Now 80% of primary care physicians are unwilling to care for chronic pain patients, even for basic care. The focus on restricting prescriptions is a solution for a non-existing problem. If patients use their medications appropriately according to multiple large studies, there is very little risk of SUD for chronic pain patients. The real crisis is lack of access and treatment for 20 million Americans living with high-

impact chronic pain. Yet, we continue not to be represented. We are the biggest stakeholder and we are not represented anywhere. Thank you.

Dale Barnes
Intractable Pain Patient

I would like to reiterate a couple of the points that were just made. I am an intractable pain patient. I'm also a son, a brother, and an uncle. I wanted to point out that it is very distressing to see that once again, there are not patients in this Opioid Workgroup. I hope that can change. I don't know if it's possible. Secondly, we have got to get to addressing the patient outcomes. This is critical. As the prior commenters mentioned, doing a cheer because you have lower prescriptions doesn't identify what's going on with the people who have been removed from their pain medicine. Also, y'all mention stakeholders quite often. I question the involvement of those involved with the physicians involved with opioid prescribing. You also mentioned that you're trying to not include any bias in this workgroup. If Physicians for Responsible Opioid Prescribing (PROP) is involved in this workgroup, there is inherent bias. For instance, there is an article of the *Journal of the International Association for the Study of Pain* (*IASP*) on Jane Ballantyne and PROP wanting to reclassify LTOT patients as a completely new Diagnostic and Statistical Manual of Mental Disorders-V (DSM-V) code. If that is successful, that's going to have a humongous detrimental impact on intractable chronic pain patients and their future treatments. Physicians for Responsible Opioid Prescribing, or PROP members, these folks don't believe pain exists—plain and simple. That is inherent bias. They do not have a role. They are not a stakeholder in this. Pain patients, we are, and our providers. I hope that there is considerably less involvement by PROP members in this new Guideline or enhanced Guideline. I hope that you're able to somehow include patients in some way, shape, or form in this Opioid Workgroup. Thank you.

David Prologo, MD, FSIR, ABOM-D
Interventional Radiologist, Emory University School of Medicine
Speaking on Behalf of the American College of Radiology

My name is David Prologo. I'm an Interventional Radiologist in the Emory University School of Medicine in Atlanta, Georgia. Although I have personally performed thousands of procedures to manage pain and personally work as an academic analytical physician, I'm not here commenting on my own. I'm speaking on behalf of the American College of Radiology (ACR)—a 40,000-member society involved in policy and government affairs as they pertain to radiology and patient care. The reason for our comment today is that Interventional Radiologists have innovative and unique but available procedures that have been shown to decrease opioid exposure, decrease opioid consumption, decrease length of stay in the hospital for pain patients, and decrease pain measures overall essentially obviating or reducing the need for opioid exposure in many acute, sub-acute, and chronic pain conditions. This service line is supported by robust peer-reviewed literature in radiology and non-radiology journals and importantly, does not overlap with procedures performed by other sub-specialists such as anesthesiology pain medicine doctors, but rather represent unique targets that require advanced and cross-sectional imaging for guidance. We've asked to comment today so that we can make the following request that the American College of Radiology, or some representative from radiology or interventional radiology, be added to the Opioid Workgroup. The American College of Radiology or interventional radiology representatives should be involved in any generation of guidelines involving this entity or others around recommendations for alternatives to opioid therapy or opioid exposure. Thanks so much.

Melanie Ross, MPH, MCHES
CDR, US Public Health Service
Deputy Branch Chief, Health Systems and Research Branch
Division of Overdose Prevention
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Good afternoon, everyone. This is CDR Melanie Ross with the Division of Overdose Prevention. I previously presented on the Opioid Workgroup update. I just wanted to make note that there are patients and family members who have chronic acute pain represented on the Opioid Workgroup. I did not call out that perspective due to confidentiality. This was disclosed via CVs from the nominees or through emails from nominees. On the Opioid Workgroup, we do have this perspective represented. I just did not call that out explicitly in announcing the list of members and their affiliations. So, I just wanted to make that note so that was clear.

Fred Brown
Long-Term Chronic Patient
Pain Patient Advocate for Pain Patients' Rights

I have been a long-term chronic pain patient for over 2 decades. The use of opioid medications for 22 years has been imperative and only prescribed by my pain management physician. I am a pain patient and an advocate for pain patients' rights. I have brief comments I would like to share with you about why the 2016 Guideline should be changed. I believe such added stress has been brought about because of the Guideline that many of the patients who have been injured are no longer with us because they could not obtain legally prescribed medications and because of this began to find street drugs to relieve their pain or worse, used suicide to relieve their pain. We as chronic pain patients did not ask to be in this position, and each one of us has a different story to tell. I've gone through 4 cervical surgeries which have not been able to correct the problems and has brought far more severe pain to me. The Guideline from 2016 was developed, why was it that there was not one pain management physician as part of that group? Further, my understanding is that much of what was done was done in quiet, and with all respect to all of you, in a deceitful manner. If pain can be relieved, why isn't it? Why must patients have to put up with such negativity when all that we want is to find a better quality of life? I agree that drugs such as opioids may not need to be prescribed for everyone. However, there are many of us who find reduction of symptoms with the use of opioids, and in many cases at a much higher dose than 90 MME, to be highly beneficial. I believe that one who lives in chronic pain should also use other modalities with the pain medication, which can help them within their limits. I appreciate your time for today.

Leah LoneBear
Member, Chronic Illness Advocacy & Awareness Group, Inc.

Hi. My name is Leah LoneBear. I am a member of the Chronic Illness Advocacy & Awareness Group, Inc. (CIAAG). One comment that I would like to make is that I am absolutely struck by the lack of mention in a moment of silence for people who suffer chronic pain and who have lost their life to chronic pain. Very quickly I will try to get this statement in. Research shows that CDC knew beforehand that harm would be the result of the 2016 Guideline and chose to procced. PROP presented this theory to the Food and Drug Administration (FDA) and was rejected for good reason, but then was accepted by the CDC. It is demonstrable that the National Pain Strategy and best practices is a study being conducted on pain patients against their will because no one in true pain can bear being removed from meds for long-term studies, so the

only way to acquire studies is to force patients off meds. These entities have a goal of study, experimentation, forced tapers, alt treatments, and pushing all patients onto buprenorphine (BUP), or implanting them with a spinal cord stimulator (SCS). This has caused a human genocide of senseless, preventable suffering, death, and suicide. What has become treatment of pain in American violates the Nuremberg Code of Ethics, 42 US Code 35, and the civil and human rights of all innocent patients who have been harmed or killed because of this. Since the guidelines, there has been nothing but a landslide of papers written, theories published, opinions formed—all drowning out the very real voices of people in pain crying out for mercy, sanity, compassion, and equity to return to a treatment of pain patients who are treated unlike any other patients that exist. The American Medical Association (AMA) has taken a stance and laid out in no uncertain terms what they feel should be done in regard to guidelines in keeping with the AMA. I insist that the CDC immediately withdraw the guidelines and restore care for patients and let their doctors take care of them. Now would be the time for the CDC to own what they have done and what happened. You are responsible for the preventable, disabling, suffering, death, suicides, loss of life, quality of life, jobs, relationships, dreams, goals, and being able to perform activities of daily living (ADL) in people who were fully functional on pain medication but were destroyed by your hand and called “collateral damage.” Do the right thing. Tell the illicit truth. It is not our prescription-administered medicine causing the crisis in this nation. It has been and is illicit drugs. While all the money and power of our government and alphabet agencies are busy scapegoating pain patients, the real killer is still out there and the numbers of deaths from illicit drugs and polypharmacy climb while you, as has been the mode from the start, failed to factor in the shattering role that alcohol plays in this nightmare. Until it is addressed head-on as a major factor, people will continue to die. Thank you for your time.

Anne Fuqua
Former Registered Nurse

My name is Anne Fuqua. I have no associations or conflicts of interest. I worked as a Registered Nurse (RN) prior to becoming disabled. I am a long-term high-dose patient who has benefitted greatly from these medications. I appreciate the fact that the CDC is putting forth the effort to revise its guidelines. I have several concerns, though. First, there is a strong focus on MMEs. We need to look at the impact that dose has on the patients before making a judgment as to whether the dose is a good or bad thing. Patient outcomes, not MMEs, should be the primary metric. While 1000 MMEs sounds incredibly high, I have no side effects, normal endocrine function, and a quality of life for which I am incredibly grateful. I have been on this dose for over a decade and have needed no further increments. I recognize that there are times when opioids are still prescribed in cases where they aren’t needed. If you live in my world though, the world of a pain patient, things are quite different. I must travel all the way from my home in Alabama to California just to receive medical care. Patients like myself face involuntary dose reductions regardless of whether these dose reductions adversely affect our ability to function. I am in touch with one patient who was summarily discharged without even a final script [inaudible] despite his dramatic inability to function after her physician began tapering her dose. Patients are dying. Government agencies have laboriously documented prescribing, but no agency has purposely tracked and analyzed deaths among pain patients whose doses were abruptly tapered or discontinued. This is a fulltime job for me. This morning, I received a call about a patient who died earlier this week. The studies don’t communicate the human suffering brought about by the current Guideline. I believe that the call for the stakeholder interviews that was published today will be a valuable resource for the workgroup. I trust that workgroup will heed the advice and insights from the stakeholders. As I said in December, the focus on MMEs is having a dire impact on patients like myself. I pray that you will put yourselves in the shoes of

pain patients like myself and make decisions that will have an immediate and dramatic impact on those you hold dearest. Thank you for your time.

Justin [No last name stated]
911 First Responder
Combat Disabled Veteran

Good morning. I am a 911 first responder and I am also a combat disabled veteran who came home from war injured, broken, and ended up dependent on my high-dose opioid pain management medication. I quickly found myself hitting my rock bottom just like too many of my fellow service men and women. I was saved by a pain specialist who worked with me to design and implement a balanced approach to pain management. This balanced approach saved my life and for that, I am extremely grateful. I was existing, not living, and in such a state of chaos that I desperately needed that lifesaving intervention. I am here today to urge the CDC to ensure that other patients like me know that other options for chronic pain management are available and just as importantly, how to access these options. I implore the CDC to prevent more needless deaths of patients like me and my 8 Army platoon members who have since died since we came home as a result of opioid medication issues. A balanced approach to pain management and access to the most innovative FDA-approved medical technology can play a pivotal role in improving lives and preventing any future deaths for military and civilian patients alike. Thank you.

Becky [No last name stated]
Former Nurse
Chronic Pain Patient

Thank you for giving me the chance to speak. I am a Nurse. I am also a chronic pain patient. As a result of the CDC Guideline, I have had to give up my career. I am not the mother I want to be, I am not the spouse I want to be, and in general, I am not the person that I once was. I really wish that doctors were able to have a doctor-patient relationship without government over-reach into the doctor's office. All patients should be able to get individualized care from their physicians without stigma and without being judged. I don't know what it's going to take for this to happen, but if something doesn't get fixed soon, then even more people are going to die without medications available to control these symptoms and give people their quality of life back.

Chris Booth
Registered Nurse
Chronic Pain Patient

Good morning and good afternoon. Chair Whitaker and distinguished board members, it is both an honor and a privilege to provide public comment before you today. My name is Chris Booth and I am from Madison, Mississippi. I'm a husband, a father, a son, a brother, a friend, and a chronic pain patient. I've worked in healthcare for more than 23 years, including 13 years as a Registered Nurse. Tragically in 2011 while heading to work in the operating room, I was hit from behind by a gentleman who fell asleep driving an 18-wheeler on the interstate. Over the next 3 years, I underwent 6 surgical procedures including a multi-level lumbar fusion and an SI fusion. At one point, I was taking 16 different medications to help control my pain. After years of treatment with physical therapy, water therapy, transcutaneous electrical nerve stimulation (TENS) unit, chiropractic care, and multiple epidural steroid injections, I found lasting, meaningful pain relief with spinal cord stimulation. The pain relief I experienced over the past six

and a half years with my spinal cord stimulator has given me a second chance at life. I no longer take any medications, I'm able to sleep through the night, and I'm physically active again. I've been blessed with the ability to return to my field of Nursing to care for others in pain. My wife and I were able to have another child. I wish I would have known there were FDA-approved options available earlier. Men and women of the CDC, as you are updating your guidelines, please be sure that the public knows about FDA-approved therapies and technology as options for chronic pain such as spinal cord stimulation. Thank you again for your time and consideration today.

Andrea [No last name stated]
Patient with Multiple Chronic Comorbidities
Past Executive Director of a Chronic Pain Organization
Medical Malpractice Consultant

I am the past Executive Director of a chronic pain organization. I also work as a consultant in medical malpractice and expert witness preparation. Thus, I have seen firsthand the power of a written guideline to influence medical-legal decisions. I am also a patient with multiple chronic comorbidities. I concur that there is an absolute lack of attention to patient outcomes, patient experiences, or clinical experts. These perspectives should be available to the CDC to provide critical data that currently is uncounted and unappreciated. With the 2016 Guideline, CDC created a crisis of terrified clinicians across the nation who find themselves pulled between the needs of their patients and the terror of the CDC Guideline being applied as a judgment of their practice standards. All of this must be reversed if we are to stop the crisis and suicides of chronic pain patients across the nation. I daily assist abandoned patients in crisis who are facing unbearable pain-preventable diseases who experience an abrupt discontinuation and often are at risk of suicide. I receive multiple letters and emails of these suicidal patients daily. In my opinion, the biggest harm from the Guideline was the reference to specific MME thresholds, which became weaponized via multiple agencies and stakeholders. The CDC is focused on reducing the quantity and dose of opioids in harming patients, but also is missing the entire cause of the current overdose crisis. Last, I'd like to question the emphasis on epidemiological data that is relying on a reductive set of variables that fail to appropriately characterize patients and their needs. The CDC just reported on only 3 things: insurer, dose, and single diagnosis code. These 3 elements are inadequate to capture the complexities of patients across the nation. Also lacking here is an appreciation of multiple chronic comorbidities. Like everyone else has said, I have seen zero data on the impact of your policies. What happens when pain is untreated? What is your role in monitoring patient outcomes? Why has the CDC not focused on the traumatic impact on individual patients since the guidelines were published? To those of us who are working on the frontlines of patient care, these guidelines have been catastrophic. I am imploring you today to remedy these tragic outcomes, implement the recent AMA resubmission, and restore pain care across America. Thank you.

Scot Faulkner
Photobiomodulation Foundation

I am Scot Faulkner with the Photobiomodulation Foundation. Thank you for this opportunity to offer suggestions on updating and expanding the *CDC's Guideline for Prescribing Opioids for the Management of Chronic Pain*. The Foundation endorses your more holistic approach by placing opioid use into a broader set of options for managing pain. We also endorse the non-opioid treatment recommendations highlighted by Dr. Christian Mikosz's slide #23. These non-opioid treatments should include restorative therapies as outlined in the Department of Health and Human Services *Pain Management Best Practices Inter-Agency Task Force Report* issued

on May 9, 2019. On September 20, 2019, that report's holistic approach was validated in the Centers for Medicare and Medicaid Services (CMS) *Action Plan to Prevent Opioid Addiction*. Both reports outlined how prescribing opioids should be part of a broader integrated approach for pain management. There are many restorative therapies that have been proven effective in pain management, either as standalone treatments or adjunctive to opioids. These should be considered by this board. One of these therapies is photobiomodulation, or PBM. The Multinational Association for Support of Care in Cancer (MASCC) established PBM therapy as the standard of care for treating pain and side effects related to cancer chemotherapy and stem cell transplants. The Academy of Laser Dentistry (ALD) includes PBM therapy in their standard of care for treating pain and reducing opioid use during oral surgery. PBM therapy's efficacy is supported by over 700 randomized clinical trials (RCTs) and 6000 research studies, many published in leading scientific journals. There have been 100 million successful patient treatments without any documented side effects. PBM is FDA-cleared. PBM is red and near infrared light. When directed at the parts of the body with the right intensity, PBM stimulates mitochondria to repair and restore cell functions and reduce inflammation. It is a natural process aiding a natural process. PBM is being used in veteran's hospitals for reducing opioid use in pain management. Please incorporate restorative therapies as part of your broader pain management focus when updating and expanding the CDC Guideline and your public awareness materials. Thank you.

Shanta Whitaker, PhD, MPH
Director of Scientific Affairs
Voices for Non-Opioid Choices

Good afternoon and thank you to the Board of Scientific Counselors for giving me the opportunity to speak today. My name is Dr. Shanta Whitaker and I am the Director of Scientific Affairs at Voices for Non-Opioid Choices, a non-partisan coalition dedicated to preventing opioid addiction before it starts by increasing patient access to non-opioid therapies and approaches to managing acute pain. Our coalition is fully invested in doing our part to curb the US opioid epidemic by ensuring that patients are educated on and have access to all safe, effective, and available non-opioid options to treat acute pain, especially after surgery. We strongly support the development of acute pain management guidelines. Our coalition is especially concerned with acute pain management that occurs perioperatively, as surgery-related pain has been established in the literature as a gateway to opioid abuse, misuse, and dependence. In order to close this gateway, we need guidelines that offer procedure-specific, standardized, non-opioid-driven, multi-modal approaches to manage patients' acute pain throughout the course of their surgical journey. One reason we have been unable to move away from opioids as a standard of care is a lack of standardized protocols by procedure and centered on non-opioid options. Clinicians develop their own protocols, and these protocols vary greatly from hospital to hospital. CDC-led standardization of procedure-specific, non-opioid, multi-modal protocols will aid in consistent, well-managed acute pain for all patients undergoing surgery with little to no opioids. We appreciate the opportunity to provide feedback and applaud the Board of Scientific Counselors' effort and look forward to learning about how the CDC will recommend managing acute pain in the future. Thank you.

Peter Staats, MD, MBA
Former Founder & Chair of the Pain Division at Johns Hopkins
President Elect, World Institute of Pain
Medical Officer, Pain Practice

I'm Dr. Peter Staats. I'm the Former Founder and Chair of the Pain Division at Johns Hopkins and am currently the President Elect of the World Institute of Pain (WIP). I am also the Chief Medical Officer of the largest pain practice in the United States with offices in 10 states. I also was fortunate enough to have served on the HHS Pain Task Force, where we spent a considerable amount of effort and time trying to come up with the best practices for pain in the United States. I think that it's important that we continue to balance the issues of the opioid epidemic and opioid crisis that we've been hearing about with the realities of taking care of patients with chronic pain. The Health and Human Services Best Practices Task Force really did its best to try to balance the various issues. Specifically, one of my areas of interest similar to some of the patients who were discussed, has been on the use of neuromodulation approaches. In specific, the Interventional Pain Task Force looked at interventional therapies, including spinal cord stimulation and other neuromodulation therapies and found that there are multiple randomized controlled trials demonstrating the safety and efficacy of this approach. It's important that the CDC incorporate these guidelines, carefully consider them, and use evidence-based approaches like the one we developed in the HHS Task Force, but other interventional guidelines as well. It's also important that we expand opportunities for patients to have alternatives to opioids while not mischaracterizing patients as being addicts or having other types of problems. Finally, I'd like to request that we encourage earlier referral to pain physicians so as mentioned earlier we don't get into the unnecessary use of opioids so we can offer alternative strategies at an earlier phase on the patient care continuum. I thank you very much for considering these points and hope to have continued transparency from the CDC in trying to come up with the best strategies for our patients in the United States. Thank you.

Mary Miller
Chronic Pain Patient

Thank you for giving me the opportunity to testify in front of you. My name is Mary Miller. I'm from Eastsound, Washington. I am a chronic pain patient. My pain journey started in 2006 when, like many chronic pain patients, I saw numerous doctors, had countless medical tests, and have endured more therapies and medications than I can remember. My condition robbed me of my active life. I have sought both traditional and non-traditional therapies. I was barely able to walk without excruciating fire down my leg and my lower back. Finally, in 2013 seven years later, by chance I was given the opportunity to try a spinal cord stimulator and it was life-altering. It has allowed me to return to an active life of gardening, yoga, camping, and activities that I never thought that I would experience. But it is a tool in my toolbox along with other therapies. I am a person that is in chronic pain and there is no surgery that will cure me at this time. However, I say this to you members of the CDC, that I wish I had known that an SCS and therapies like it were available so that I didn't suffer for 7 years. In my pain journey, I missed out on so much. So again, as you're updating your guidelines, I hope that you make it a priority that the public knows that the FDA has approved therapies and technologies as options such as a spinal cord stimulator. Thank you.

Cammie LaValle
Advocate for Proper & Viable Care for People Suffering with CRPS/Rare Diseases/Chronic & Intractable Pain

I appreciate this opportunity. I have incurable rare diseases that have no FDA-indicated treatments and involve some severe pain. One of the diseases is complex regional pain syndrome (CRPS), also known as reflex sympathetic dystrophy (RDS) that was the result of a carpel tunnel surgery. Although I have tried non-opioid medications in addition to epidurals, injections, and I still have nerve blocks—what has happened with some of those injections and nerve blocks is the disease has spread throughout my body, including my breasts. That is a direct result from these interventional techniques, and these nerve blocks, and injections. I'm still forced to get these nerve blocks that have made the disease spread. I responsibly take my opioid medication. I'm also disabled, and am on palliative care status, and I am being force-tapered, which I am exempt from the guidelines. I happen to live in Minnesota. Right now in Minnesota, if a physician does not follow the quality improvement program to meet the 90 MMEs or 50 MMEs, they could face punitive action. They could be disenrolled from being a provider. So, the physicians throughout the United States, and I can talk for my state in Minnesota, they are deeply concerned of losing their licenses, losing their ability to practice and treat Medicaid patients, Medicare patients, state program patients. And they're concerned of the DEA and are even force-tapering palliative care patients like myself. I appreciate non-opioid medications and if it helps people, including the stimulator. But due to my inoperable spine damage, I cannot get a stimulator. And so if I could, I would do these things. What I'm asking the CDC to do, in addition to other people who have asked this, and I really want to focus on misinterpretation and misapplication of the Guideline, if the CDC does not intervene with the state departments of health and human services and stop them from continuing to misapply these guidelines, it's just going to get worse for people like myself with intractable pain documented in our files and palliative care patients. So, thank you for your time and please do something on a serious note. Take serious actions. Address this with the states so they do not continue to harm patients, which has led to suicide. Thank you for your time.

Frances Hunt
Chronic Pain Patient

Hi. My name is Francis Hunt. I live in Newport News, Virginia. I was a Registered X-Ray Technician, Ultrasound, and Mammographer. I did mostly ultrasound for almost 30 years. I loved my work, but the pain came in 2009 and I was diagnosed in 2011 with fibromyalgia. I also have some osteoarthritic problems. I have bone spurs in the facets, so they rub on all of the nerves and it's very painful. I was on opioid therapy, twice in fact, long-term opioid therapy. The first time I was told to stop the opioids in a 3-week span. That was like a living hell. I couldn't believe it. If I hadn't gone online and tried to find out what could help me quickly—it was recommended kratom. I ordered kratom and I took it—the minimum amount because I didn't take it before. Believe me, it got me through that. I don't know how I survived it, but I did. But anyway, later on I went to a different pain management group where the other fibromyalgia people in my area had been going to, so I went to that group. A year later, that doctor left the practice. So anyway, I was on a long taper of over 11 months and a new doctor that initiated that. That was helpful to stop the opioids long-term over a long period of time instead of quickly abruptly stopping it. But my point is I read an article just recently Dr. Paul Christo, and it was published in 2020 summer *Journal of Law, Medicine & Ethics* (*JLME*). He wrote that long-term opioid therapy was shown to be beneficial and it listed fibromyalgia as one of the groups that it was beneficial for. So, my concern is what next? Because there's no doctors in my area now that will even treat fibromyalgia pain. I mean, I can call them up and they say, "Yep. We don't

treat fibromyalgia pain." And so, you know, I'm at a loss here. I'm trying to stay calm as much as I can possible, but it has really taken my life away. I mean, I was so active. I was mountain biking with my husband, and going and getting the grandkids, and doing lots of things with them. That stopped. It all stopped and it's like I'm not even me anymore. And so, I want my life back. I am so sorry for the families who have lost their loved ones due to opioid abuse. I'm so sorry that they did lose their loved ones. I really am. But did they know that this abrupt stop that the 2016 guidelines would change people's lives? And in some cases, people took their own lives and are still doing it because they are in so much pain. If there is a way we could solve both of these problems, I would be so happy. I would be so happy that this would happen. In the meantime, I really think they need to allow people with chronic pain to stay on the opioids until a proper non-opioid medication that is effective and will result in getting people's lives back on track, then I'll be happy to go off opioids, which I'm not on them anyway right now, but if I were, I'd be happy to go off of it if there was a non-opioid that was just as effective. But I'm like the others. I've gone through epidurals and nerve blocks and I have a TENS unit. I was offered a spinal cord stimulator, but then somebody came and closed the business. Now I have nothing. Nothing to go on. So if someone could please help us, I would really appreciate it. I just want my life back. You know, I was a caregiver and I loved it. I was taking care of my 90-year-old father at the time and the pain was so bad, I had to give up the care of him and luckily, I had another family member who took over the care for him until he passed away 2 years later. But to see him look at me and he knew I was in such horrible pain, I could see the pain on my father's face, and that was horrible. So, anyway, I appreciate this group meeting, but I just want things done right. I want the 2016 guidelines to be abolished and start over from scratch again, okay? So, thank you for the time that I've had to speak. I appreciate it. Alright. Thank you.

Michelle Farrell
Safety Coalition for Patients
Chronic Pain Patients

My name is Michelle Farrel. I work with the Safety Coalition for Patients, an advocacy group. I have a couple of points I'd like to address. The MMEs have been addressed, but we need to consider patient diagnoses and their individual attributes in order to get a more complete picture. An example is myself. I've had gastric bypass. I don't absorb. I live in Arizona. Our state has essentially utilized the guidelines and made them law. So, I have prescribers who are scared to prescribe. They have told me this point blank. I have pharmacists who will refuse to fill for similar reasons that appear. That's something we need to look at is apart from the diagnoses, what other data points can we receive that give attributes, diagnoses codes, and such. When we talk about the number of prescriptions that are written, I don't hear much about the fact that we cannot refill these scripts, so a 12-month period for one pain prescription is 12 versus a non-pain prescription would be 3 or 4 depending upon the number of refills potentially from one script number. So we kind of get a false look when we talk about the number of prescriptions per population, et cetera because we don't take that into account. That needs to be aggregated up within the data and the subsets to see if it is the same script month over month and it's just a new number. I would think there is a way to compare the data for that. Functionality people have addressed. We definitely need to be looking at more of the outcomes than just the MMEs because we all handle medication differently, we metabolize differently, there's been furtherance of genetic studies and the metabolism and whether certain meds are effective based upon gene studies. That is expensive to do, but many patients cannot do that or their doctors won't. That also is, when we talk about all of the alternative cares, we have to look at, and it was touched upon, the availability and the cost. I live in an area of Arizona that is on the cusp between rural and urban, so I'm kind of in this weird place. There's a few pain

management doctors close, but there can be about a 30- to 40-minute drive. If you look at alternatives, they're not necessarily available as well or affordable at the rates that are there. Again, insurance companies don't cover things like that. I think for the touchpoints for those, I think if we could start somehow getting those in, it would give us a much better clear picture for what we are striving for. Thank you for your time, and hopefully I didn't go too far over, and I hope everybody has a good day.

Chris Ferguson, MD
Board-Certified Interventional Pain Physician
Board-Certified in Pain Management and Anesthesiology

Hi. My name is Chris Ferguson and I am a Board-Certified Interventional Pain Physician, Board-Certified in Pain Management and Anesthesiology. I think I will just summarize what everyone is saying. Patients are being denied access. I feel that patients are not being referred as quickly as possible in the treatment pathway to a pain physician that knows their medication management needs to be addressed safely. As the other patients have spoken about, to have access to proven technologies like injections and spinal cord stimulators to treat a whole host of conditions. Also, a pain physician, it is their specialty to coordinate care between the appropriate surgical sub-specialties, behavioral health, psychiatric health, and physical therapy. So, I would urge the committee to have pain physicians on the committee, because really that is the specialty of pain management. Thank you.

Nimesh Patel, MD
Interventional Pain Physician
Board-Certified in Pain Management

Hi. This is Dr. Nimesh Patel. I'm an Interventional Pain Physician. I'm Board-Certified in Pain Management and I have Fellowship training from the Cleveland Clinic After taking care of thousands of patients over the last 25 years, I recognize the value of a multidisciplinary pain approach. I strongly encourage the Opioid Workgroup, as well as the Board of Scientific Counselors and the National Center for Injury Prevention and Control to include the following recommendations in the forthcoming guidelines:

1) Adopt well-researched and established intervention pain guidelines, because these evidence-based FDA-approved intervention therapies are effective in decreasing pain, decreasing the need for opioid, and increasing function. These have been the key for me over the last 25 years in helping thousands of patients avoid opioids or decrease opioids in our communities. This is mentioned in the CDC's primary objectives in the initial guidelines.

2) Encourage early referral to pain specialists. Every patient deserves a comprehensive evaluation by a pain specialist because we have better diagnostic and therapeutic tools at our disposal that are not necessarily available to the primary care doctors. Early referral means referring 3 months after symptoms, and ideally before the patient is even started on opioids.

3) Include the *HHS Pain Management Best Practices Inter-Agency Task Force*, particularly Section 2.4 Intervention Procedures, in the CDC Guideline as has been alluded to by several patients as well as several physicians. Interventional therapies, including radiofrequency ablation, spinal cord stimulation, and spacers have the best data in terms of decreasing opioids, reducing pain, and improving function. As an example, spinal spacers

have been shown to reduce the need for opioids in 85% of patients at 5 years, and this is critical.

4) Finally, as we move forward, I hope there is transparency. It has been extremely frustrating to myself and several other doctors who are also waiting online to actually provide a comment today. The original publication of this meeting was buried inside the *Federal Register*. This is unfortunate in that many people did not even know how to dial in or find the registration information. Going forward, be more transparent and honestly seeking opinions from people on the frontline. There are many societies who are willing to comment and would welcome public comment, as well as a private meeting with the CDC from multiple societies and leaders in the field who are on the frontlines who have amazing experience over decades that really could bring the CDC Guideline to the state-of-the-art as opposed to continuing to advocate for meditation, acupuncture, and tai chi, all of which have a place but will not necessarily solve the problems of patients who you heard on the call today.

With that, I am thankful for the opportunity and for allowing me to bring up my comments.

MDMA
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July 28, 2020

Via Electronic Submission - NCIPCBSC@cdc.gov

Gwendolyn H. Cattledge, Ph.D., M.S.E.H.
Deputy Associate Director for Science
National Center for Injury Prevention and Control (NCIPC)
Centers for Disease Control and Prevention (CDC)
4770 Buford Highway, NE
Mailstop S106–9, Atlanta, GA 30341

RE: Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC/NCIPC) - Meeting, July 22, 2020

Dear Dr. Cattledge,

On behalf of the Medical Device Manufacturers Association (MDMA), I am pleased to submit MDMA's comments in response to the BSC / NCIPC virtual meeting on July 22, 2020. We appreciated the opportunity to participate in that meeting and receive an update on findings from the stakeholder public comments related to acute and chronic pain management as well as the formation of an opioid workgroup. We also appreciated the opportunity to hear oral public comments. We thank you for the opportunity to provide our written comments following the July 22nd meeting.

MDMA is a national trade association that represents hundreds of companies in the field of medical technology. Our organization provides educational and advocacy assistance to innovative and entrepreneurial medical technology companies, and it is our mission to ensure that patients have timely access to safe and effective medical products that improve health outcomes. Our members, the majority of which are small to mid-sized, research driven medical device companies, have a strong record of delivering innovative therapies to patients suffering from chronic diseases and life-threatening conditions while lowering the cost of care.

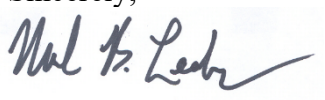
There are hundreds of Food and Drug Administration (FDA) approved or cleared medical devices in the marketplace that can treat acute and chronic pain or reduce pain through minimally invasive procedures. Other medical device technologies have been proven to reduce addiction, dependence or withdrawal symptoms as well as the ability to monitor key vital signs and offer care teams early identification of deteriorating patient conditions. Commenters at your July 22nd meeting discussed using medical devices as a part of their pain management treatment protocol and their positive experiences with a number of devices for acute and chronic pain management. Medical devices are a recognized, evidence-based, safe and effective pain

treatment option, and they should be more accessible to pain patients as they have a demonstrated ability to reduce opioid use and abuse.

We are pleased to hear that you are considering a revision to the 2016 Guideline for Prescribing Opioids for Chronic Pain. As we commented in response to the request for stakeholder comments on the management of acute and chronic pain (docket number CDC-2020-0029) the CDC, as the nation's preeminent body charged with protecting America from health, safety and security threats, is well positioned to lead a coordinated and connected effort that enables greater patient access to and awareness of opioid-sparing medical devices. The 2016 guideline includes references to "alternatives" but does not detail the hundreds of evidence-based, FDA cleared or approved medical devices available to pain patients. An update should appropriately detail the role of medical devices in treating pain. As a Health and Human Services (HHS) Pain Management Best Practices Inter-Agency Task Force report detailed, medical devices are a key component to a multimodal approach to pain management. We encourage the BSC, NCIP to recognize the role of these technologies as you move forward with the opioid workgroup and consider revisions to the 2016 guideline and other policy recommendations impacting chronic and acute pain.

Thank you for the opportunity to provide our perspective. As an addendum to this letter, I've also attached our June 16, 2020 comments to Dr. Robert Redfield in response to the request for comment on the management of acute and chronic pain, docket number CDC-2020-0029. Please let me know if you have any follow up questions or concerns. We look forward to working with you on behalf of all the patients we mutually serve.

Sincerely,



Mark B. Leahey
President & CEO, MDMA

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July 27, 2020

Via electronic submission: NCIPCBSC@cdc.gov

Robert R. Redfield, M.D.
Director
Centers for Disease Control and Prevention
1600 Clifton Road, NE
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Atlanta, GA 30329

Dear Dr. Redfield,

Abbott welcomes and appreciates the opportunity to comment on the Centers for Disease Control and Prevention (CDC) Management of Acute and Chronic Pain Guidelines.

Abbott is committed to helping people live their best possible life through the power of health. For more than 130 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 107,000 Abbott employees are working to help people live not just longer, but better, in the more than 160 countries we serve.

As a leading medical technology and nutrition manufacturer, we seek to ensure that the CDC Guidelines promote patient access to high-quality healthcare innovations that address unmet medical needs and improve health outcomes. We recommend that the CDC explore alternatives to incorporate non-opioid pain management therapy alternatives into its updated Guidelines, specifically including neuromodulation and interventional pain procedures. We advocate that incorporating these procedures earlier in the treatment continuum for appropriate patients may potentially avoid potential chronic opioid therapy. We appreciate the CDC's request for public comments and advocate that evidence-based therapies are included in the revised Guideline as they may help avoid prescription opioid use.

Neuromodulation, specifically spinal column stimulation (SCS) and Radiofrequency Ablation (RFA) , are established, evidence-based, non-opioid therapy options for the management of chronic neuropathic pain conditions such as failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS) that is refractory to more conservative treatments.[1] Both technologies have been covered by CMS and most commercial payers for decades and are

1 Deer TR, Mekhail N, Provenzano D, et al. The appropriate use of neurostimulation: avoidance and treatment of complications of neurostimulation therapies for the treatment of chronic pain. Neuromodulation Appropriateness Consensus Committee. Neuromodulation. 2014;17(6):571-597; discussion 597-578.

available as covered benefits to appropriate patients when published coverage criteria are fulfilled.[2]

As the evidence demonstrates, SCS and RFA offer important non-opioid treatment alternatives for patients with neuropathic pain. It is noteworthy that in 2018 healthcare providers wrote 168.8 million prescriptions for opioid pain medication, and while this amount represents a decrease over previous years, this data may indicate that many physician specialties may be unaware of the range of other potential treatment options that exist prior to prescribing opioids which could be addressed in updated CDC Guidelines.[3] Further, real-world evidence demonstrates that SCS may lead to a reduction in the use of opioids for chronic pain patients, which is the goal of the CDC's Guidelines.

Therefore, as part of its review of policies and practices to encourage the use of non-opioid treatments, Abbott suggests that the CDC incorporate SCS and RFA as treatments for appropriate patients in alignment with FDA labeling to avoid potential chronic opioid therapy. We also suggest that the CDC develop incentives for appropriate referrals of patients with chronic pain to comprehensive pain management practices for consultation and evaluation prior to the administration of opioids for chronic conditions. Conditions such as post laminectomy syndrome and complex regional pain syndrome I and II could benefit from such a referral.

In addition to the large body of existing clinical evidence that supports SCS, Abbott has sponsored two of the three most recently published Level-1, comparative randomized controlled trials (RCTs) in this therapy space.[4,5] Recent evidence also indicates that SCS provides the opportunity to potentially stabilize or decrease opioid usage.[6] Additionally, it is important to note that published studies demonstrate that neuromodulation retains its efficacy over multiple years[7] which often includes opioids for which there is limited evidence of long-term effectiveness.[8,9,10]

Interventional pain procedures such as RFA applications are also an evidence-based, non-opioid therapy that should also be considered in the updated CDC Guideline. Recently published

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2 https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

3 https://www.end-opioid-epidemic.org/wp-content/uploads/2019/06/AMA-Opioid-Task-Force-2019-Progress-Report-web.pdf

4 Deer, T, Levy R, et al. (2017) Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. Pain, 158 (2017) 669–681.
5 Deer S, Slavin K, et al. (2018) Success Using Neuromodulation with BURST (SUNBURST) Study: Results From a Prospective, Randomized Controlled Trial Using a Novel Burst Waveform. Neuromodulation, 21(1):56-66.
6 Sharan et al. (2017) Association of Opioid Usage with Spinal Cord Stimulation Outcomes. Pain Medicine, 0: 1–9 doi: 10.1093/pm/pnx262.
7 Chakravarthy, Pain Physician 2018; 21 507-513 ISSN 1533-3159, Reframing the Role of Neuromodulation Therapy in the Chronic Pain Paradigm.
8 Finnerup, Attal, et al. (2015) Pharmacotherapy for neuropathic pain in adults: a systematic review and meta-analysis. Lancet, 14:162–73.
9 Krebs, et al. (2018) Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial. JAMA, 319(9), 872-882.
10 Sharan et al. (2017).

treatment guidelines address the appropriate patient selection criteria and effective use of this therapy that should also be considered by the CDC in the updated Guidelines.[11,12]

In summary, evidence indicates that use of SCS earlier in a patient's treatment could help reduce opioid use while controlling their chronic pain. For instance, a large, observational real-world study utilizing insurance claims data by Sharan and colleagues demonstrated that earlier consideration of SCS before escalated opioid usage has the potential to improve outcomes in complex chronic pain. The study also found that opioid dosage across the population increased significantly over the year prior to SCS implant. Historically, patients who receive SCS tend to be high-dose opioid users because the "stepladder" approach places neurostimulation after opioid therapy.[13] Alternatively, if clinicians could intervene with SCS earlier in the treatment continuum, before opioid use has reached extreme levels, outcomes could be improved, according to the findings of Lad and colleagues. In their retrospective observational study, a shorter delay in the time from chronic pain diagnosis to SCS implantation may make it more likely SCS will achieve lasting therapeutic efficacy. The Lad study also found that longer delay between diagnosis of chronic pain and the utilization of SCS therapy correlates with increased opioid prescriptions based on real-world claims analysis.[14]

Use of high dose opioids has been proven in real world evidence to prolong postoperative stays, reduce improvement in pain scores, and increase ongoing healthcare costs. Abbott therefore encourages the CDC to continue efforts to provide patients access to non-opioid pain management alternatives, such as neuromodulation and interventional pain procedures, and explore ways to encourage earlier application of neuromodulation therapy.

We appreciate your consideration of this request. Please feel free to contact me if you have any questions or need additional information regarding this topic.

Sincerely,

Allen W. Burton, MD

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11 Manchikanti, L, et al. (2020) Comprehensive Evidence-Based Guidelines for Facet Joint Interventions in the Management of Chronic Spinal Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines. Pain Physician, May/June 2020, 23: S1-S127.

12 Cohen SP, et al. (2019) Reg Anesth Pain Med 202; 0:1-44. Doi 10.1136/rapm-2019-101243

13 Sharan et al. (2017).

14 Lad et al. (2016) Longer Delay from Chronic Pain to Spinal Cord Stimulation Results in Higher Healthcare Resource Utilization. Neuromodulation.

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Victor L. Nannini, DDS, FACS
President

Scott Farrell, MBA, CPA
Executive Director

July 29, 2020

Arlene Greenspan, DrPH, MPH, PT
Associate Director for Science
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway, MS F63
Atlanta, GA 30341

Dear Dr. Greenspan:

Thank you for the opportunity to comment on the July 22, 2020 meeting of the Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC, NCIPC) at the Centers for Disease Control and Prevention. On behalf of the American Association of Oral and Maxillofacial Surgeons (AAOMS), the professional organization that represents more than 9,000 oral and maxillofacial surgeons (OMSs) in the United States, we appreciate your efforts to help mitigate the opioid epidemic while balancing the needs of providers and patients when treating chronic and acute pain. Finding the appropriate balance is a challenging effort, and AAOMS would like to provide whatever assistance we can as you continue your deliberations.

As you are aware, oral and maxillofacial surgery is the surgical specialty of dentistry. As such, management of our patients' pain following invasive procedures is an important aspect of providing the best quality patient care. As lawful prescribers, we know, when used appropriately, prescription opiates enable individuals with acute and chronic pain to lead productive lives and recover more comfortably from surgical procedures. We also recognize, however, that pain medication prescribed following oral and maxillofacial surgery is frequently the first exposure many American adolescents have to opioids, and roughly 12 percent of all immediate-release opioid prescriptions in the United States are related to dental procedures. [1] Dentists, including OMSs, have a responsibility to ensure we do not exacerbate a growing public health risk while ensuring our patients receive the relief they need following complex dental procedures.

AAOMS is committed to educating our membership about the potential for opioid abuse. We have published opioid prescribing recommendations for the management of acute and postoperative pain for the OMS patient that urge non-narcotic pain management – rather than opioids – be utilized as a first-line therapy to manage a patient's acute and post-surgical pain. These recommendations and our White

[1] Denisco R, Kenna C, O'Neil M, et al. Prevention of prescription opioid abuse: The role of the dentist. JADA. 2011; 142(7): 800–810.

Paper "Opioid Prescribing: Acute and Postoperative Pain Management" are available on our website at www.aaoms.org.

As a follow up to the July 22 meeting, we are hoping to get further clarification as to how the BSC and CDC are approaching acute pain management. It was mentioned during the meeting that the newly appointed BSC/NCIPC Opioid Workgroup – which is tasked with updating the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain – could possibly expand their efforts to include the acute care setting.

We are concerned that the workgroup is going beyond the mission defined by the BSC/NCIPC in its December 4-5, 2019 meeting, at which point, the BSC/NCIPC voted to establish the new Opioid Workgroup and determined that the primary purpose of the workgroup was to update the 2016 chronic care pain management guidelines. AAOMS believes that creating guidelines on postoperative acute pain management should not be created by experts gathered to study the treatment of chronic pain. The treatment options and outcomes for acute versus chronic pain vary widely and should not be considered together. In addition, we believe the field of dentistry is grossly underrepresented with the current makeup of the Opioid Workgroup as only one of the 22 members of workgroup has a background in dentistry, and there is no representative from the surgical specialty of dentistry.

AAOMS believes OMSs must demonstrate safe and competent opioid prescribing to manage acute and postoperative pain in their patients. Responsible prescribing of opioids must be a priority; however, we must be able to work with federal agencies to achieve this goal. AAOMS hopes that CDC will reconsider how they approach the development of opioid prescribing guidelines for acute and postoperative pain management because we believe these efforts are too important to be "tacked on" to an existing protocol. We also ask that a more comprehensive representation of the field of dentistry be included in the development of such guidelines.

On behalf of AAOMS, thank you for your consideration. For questions or additional information, please contact Jeanne Tuerk, manager of government affairs at 800-822-6637, ext. 4321 or jtuerk@aaoms.org.

Sincerely,

Victor Nannini DDS FACS

Victor L. Nannini, DDS, FACS
AAOMS President

Via Electronic Submission July 28, 2020

Gwendolyn H. Cattledge, Ph.D., M.S.E.H
Deputy Associate Director for Science
CDC National Center for Injury Prevention and Control
4770 Buford Highway, NE, Mailstop S106–9
Atlanta, GA 30341

RE: Docket Request CDC-2020-0029 Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC) Request for Comments – Opioid Workgroup

We, the undersigned academic pain medicine physicians applaud the Centers for Disease Control's opening of docket request CDC-2020-0029 and the Board of Scientific Counselors, National Center for Injury Prevention and Control public meeting and solicitation for stakeholder comments on acute and chronic pain management. A long-term solution to the opioid epidemic cannot be achieved without addressing the challenges of more effectively treating chronic pain. We look forward to working collaboratively with you to ensure pain patients have access to the full spectrum of treatment options to reduce pain, opioid related harms, and improve function.

Pain care is at a critical crossroads in America, and the need for updated guidelines and educational materials for patients and providers has never been greater. Finding *effective and sustainable options* to opioid medications for the treatment of chronic pain is a major concern to this group. Furthermore, deceasing patient's use of sedating pain medications with low efficacy and potential for drug-drug interaction is also a goal. We propose that many FDA-approved interventional pain therapies with better efficacy (as measured by Number Needed to Treat Score) are available as a long-term solution to pain management. We propose these options should be offered to patients utilizing an individualized yet flexible treatment plan under the supervision of a board-certified pain medicine physician.

Our collective cohort of academic pain physicians write today to encourage the Opioid Workgroup and the Board of Scientific Counselors, National Center for Injury Prevention and Control to include the following key recommendations in any forthcoming CDC guidelines and educational materials for pain management:

- **Adopt well-researched interventional pain guidelines –** Evidence-based pain interventional therapies can and must play a larger role in effective pain management and efforts to reduce opioid related harms. A thorough data analysis will demonstrate robust clinical evidence supporting interventional therapies ability to reduce pain, improve function and reduce oral medications.

- **Expand CDC educational materials for non-opioid treatments –** Updated patient and clinician resources are necessary to improve awareness and utilization of proven alternative therapies, especially FDA approved treatments and technologies.

- **Encourage earlier patient referrals to pain specialists –** Currently, specialists are often not involved early enough in diagnosing and treating pain syndromes, which can lead to suboptimal patient outcomes.

- **Include HHS Pain Management Best Practices Inter-Agency Task Force recommendations May 2019, particularly section 2.4 Interventional Procedures in CDC guidelines –**which

recommends early referrals of **ALL** patients for Comprehensive Pain Management evaluation with a physician versed in the diagnostic and therapeutic Interventional armamentarium.

We also respectfully request that the CDC hold a follow-up joint meeting with the leadership of our societies so that the CDC can hear directly from key opinion leaders about advancements in pain management, the multidisciplinary approach to reducing pain and improving function, and the evidenced-based technologies and therapies we utilize to improve outcomes and patient lives.

Our societies recognize that the millions of Americans currently living with chronic pain as a result of a myriad of diseases, conditions and serious injuries, are a vulnerable population of individuals who are often underserved and stigmatized for the very real problem of chronic pain.

Updated CDC guidelines and pain educational materials would represent enormous progress towards effectively managing the complex and costly consequences of pain, including its impact on the opioid crisis. We collectively urge the CDC to meet with us to help you develop forward-thinking and appropriate recommendations. We may be contacted through Dr. Shah, President-Elect of California Society of Interventional Pain Physicians (CALSIPP) at ssshah1@hs.uci.edu
.

Respectively submitted,

Shalini Shah MD
University of California Irvine

Jianguo Cheng, M.D.
Cleveland Clinic Foundation

Nagy Mikhail MD, PhD
Cleveland Clinic Foundation

Chris Gilligan M.D
Brigham and Women's Hospital
Harvard Medical School

Salahadin Abdi, MD, PhD
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Steve Cohen MD

Johns Hopkins University
Krishnana Chakravarthy, MD, PhD
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Sarah Endrizzi MD
Medical College of Wisconsin

Nalini Sehgal MD
University of Wisconsin- Madison

Miles Day MD
University of Texas- Texas Tech

Timothy Lubenow MD
Rush Medical Center

AdvaMed
Advanced Medical Technology Association

June 16, 2020

Via Electronic Mail Only
Robert R. Redfield, M.D.
Director
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Mailstop S106-9
Atlanta, GA 30329

Re: Management of Acute and Chronic Pain: Request for Comment (Docket No. CDC-2020-0029)

Dear Dr. Redfield:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments for consideration by the Centers for Disease Control and Prevention (CDC). AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings, including innovative devices, medical applications, and diagnostic tests that treat, manage, and monitor pain.

AdvaMed thanks the CDC for soliciting comments concerning perspectives on pain experiences and pain management for patients with acute and chronic pain. Though the comment solicitation sought feedback from patients, their families/caregivers, and health care providers, AdvaMed thought it was imperative for the medical device industry to also weigh in on this important issue. Medical devices are often overlooked in policy discussions regarding alternatives to opioids. For instance, the CDC Guideline for Prescribing Opioids for Chronic Pain (March 2016) refers to, and encourages use of alternatives to opioids, but provides limited direction on appropriate options for patients or providers. When referencing non-pharmacological treatments, the examples given are exercise therapy and cognitive behavioral therapy. Medical devices can and must be part of the non-opioid alternative conversation.

The opioid epidemic continues to take a tremendous toll on our country and its citizens. Given the link between opioid abuse and chronic and acute pain, significant consideration should be given to advancing care pathways that identify, address, and alleviate these types of pain, including procedures that may reduce the level of pain experienced by patients (i.e., minimally invasive procedures) and other evidence-based device interventions that can directly target and minimize acute and chronic pain, including invasive and non-invasive modalities such as spinal cord stimulators and other types of neuromodulation systems, barrier films, implantable intraspinal drug infusion pumps, cooled and standard radiofrequency neuroablation, cryoneurolysis, vertebral augmentation, electromagnetic energy, digital therapeutics, ultrasound guided regional anesthesia, and portable continuous pain relief systems.

The FDA has approved/cleared more than 200 medical device alternatives to opioids that help treat various types of pain. Despite this, the CDC's 2016 Guidance and the April 17th Request for Comment, fail to acknowledge the role of medical devices, which are used for both acute and chronic pain management and,

in some instances, are proven to reduce opioid dependence. Many of these medical devices are also considered to be reasonable and necessary and are covered by Medicare and other insurance plans.

AdvaMed is hopeful the CDC will begin to change this dynamic, and that it will do so in such a way that other federal agencies and departments take notice to align their guidelines and public communication efforts. AdvaMed encourages the CDC to be explicit in referencing the use of medical devices in future guidelines— including examples of the device types that can be used. This level of information will alert providers and patients to the presence of these medical device alternatives which may be considered as first-line alternatives to opioid use. We believe the CDC's 2016 Guideline should also be updated to instruct physicians to advise patients of the medical device alternatives to opioids available to manage pain to better enable patients and physicians to make collaborative, fully informed decisions. We also encourage the agency to provide similar guidance for managing patients with acute pain.

AdvaMed and its members are dedicated to doing our part to assist in alleviating the opioid epidemic. We encourage the CDC to partner and engage with other agencies such as the NIH, Veterans Administration, and Department of Defense to create a more comprehensive approach to addressing this crisis. We further encourage the CDC to continue to solicit input from interested stakeholders— including medical device manufacturers. Members of the medical device industry have devoted countless resources and research into the development of devices which address the needs of patients with acute and chronic pain while reducing and possibly alleviating the need for opioids. The policies underlying the consideration and use of these technologies should be evaluated in a way which makes their use a viable option for patients who are managing pain. We would like to address the following issues in our comments:

- Policies that may disincentivize use of therapies that manage chronic and acute pain and that minimize opioid abuse and misuse
- Other Options

Policies that may disincentivize use of therapies that manage chronic and acute pain and that minimize opioid abuse and misuse

AdvaMed members manufacture a variety of device-based treatments that can be used in lieu of opioids. These devices effectively manage both chronic and acute pain and may also be used to address the management of opioid addiction. The manufacturers of many of these products have developed evidence which shows a correlation between use of the devices and a reduction in the need to use and/or prescribe opioids. Despite this, many of these devices face deployment, reimbursement, and insurance coverage challenges.

Clinicians utilize a variety of devices during surgical procedures, post-surgically, and in post-acute care settings to alleviate or reduce pain symptoms. These devices which include drug-delivery devices that administer a non-systemic non-opioid analgesic directly to the site of a surgical incision, block nerve pain at the incision site, or allow minimally invasive and/or percutaneous treatment, effectively address acute and chronic pain and minimize post-procedure pain are frequently not a viable option for providers due to lack of awareness and limited coverage. We ask the CDC to implement guidelines which promote and support the use of medical devices and the ancillary procedures that facilitate their use, where such technologies have evidence of opioid reduction and/or pain alleviation.

Barriers which impede the ability of physicians and patients to gain access to the acute and chronic pain treatments that best suit their needs must be alleviated. Existing payment policies disincentivize provider use of potentially highly effective device-based pain management alternatives as a part of acute and chronic pain management strategies— making it far easier to write a prescription for potentially addictive opioids that will

be separately paid. AdvaMed recommends that the CDC partner with other agencies to resolve these payment disparities and to better allow providers who choose to deploy opioid alternative technologies in the treatment of their acute and/or chronic pain patients, especially those at risk for developing opioid use disorder (OUD), to do so without being penalized. We also support the continued tracking and production of evidence-based information by manufacturers of devices which may reduce the prescription and use of potentially addictive opioids.

Problems related to the deployment of opioid alternative devices and the inability of patients to access these innovations at the appropriate time persist. These access concerns are the result of various payment and insurance coverage issues, including delays (such as prior authorization or "step-therapy") which may require patients to undergo and/or fail drug therapy for chronic pain relief (posing possible addiction risk) prior to being able to utilize a non-opioid device-based intervention. In some instances, patients are required to undergo additional medical evaluation prior to receiving device-based non-opioid interventions for chronic pain. These additional requirements pose barriers to access and treatment delays for beneficiaries, especially those in areas with limited or no qualified providers to conduct the evaluation, prolonging their exposure to opioids and increasing their risk of addiction. The CDC should advocate for the elimination of policies that interfere with access and should promote the use of policies, such as telehealth evaluations, to minimize patient risks associated with opioid use.

The pain management issues that are the root cause of many opioid dependency issues are prevalent across patient populations—including geriatric populations. It is imperative that the CDC be proactive in working with other organizations and the stakeholder community to develop recommendations to address pain concerns across patient populations.

Other Recommendations

Materials distributed to patients should include all the available options for pain management treatment—including device based and non-systemic opioid device delivery treatments as well as recommendations regarding the referral of patients to interventional pain specialists.

Provider education and sensitivity to the risk of opioid dependence is also critical. Health care providers must be better informed of the treatment impacts that can be gained by using non-opioid devices. This will require more education regarding the range of devices and the appropriate time for their incorporation into patient treatment plans. It will also require provider education regarding the range of available device-based treatments. This education should extend to the full range of providers who are treating patients with acute and chronic pain, especially those at risk for developing an opioid dependency, including: primary care physicians other physicians, nurses, and specialists who may be involved in making recommendations to patients regarding alternative means for treating their pain. This list of providers could include neurologists, orthopods, physical medicine, emergency medicine, anesthesiologists, physical therapists, wound nurses, and others.

A variety of health care providers encounter and make care decisions for patients who could potentially benefit from an opioid alternative device. Therefore, it is critical that education regarding the epidemic, appropriate screening, and treatment options (device, drug, combinations, and restorative therapy alternatives) be made known to all care providers. Additionally, it is important for care providers to have information regarding integrating these devices into the treatment process. AdvaMed agrees with findings that were included in the 2019 Pain Management Best Practices Inter-Agency Taskforce Report (https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf) that this could be addressed through the integration of additional information into the medical school curriculum, including pain training in CME courses, and the dissemination and adoption of protocols, clinical practice guidelines, and information across sites of care. We also believe that CDC could engage with public health entities and

agencies, HHS, and physician and nursing specialty societies to collaboratively develop strategies for addressing training and education shortfalls and could incorporate this information into its guidelines.

While AdvaMed supports the use of pain specialists to assist patients in managing pain and in minimizing and avoiding opioid use, we strongly encourage the CDC to promote patient access to care by other highly trained specialists who can effectively prescribe and manage pain symptoms. We also support CDC devoting research and resources to work in the interventional pain space to allow patients with a history of chronic pain, lasting 6 months or more, to effectively access non-opioid therapies.

Patients who experience chronic pain may not seek out the care of pain physicians but instead may seek care from their primary care physician or from a physician specializing in treating the area of the body in which they are experiencing the chronic pain (e.g., a neurologist). Therefore, it is important that the full spectrum of health care providers be updated regarding the latest technologies to use in treating chronic pain. Additionally, in the context of acute pain, it is equally as important to consider the risks and outcome impacts associated with the type of surgical technique that is utilized in treating a patient's medical condition. For instance, patients may experience less post-surgical pain if treated with minimally invasive procedures when appropriate. The lower pain outcomes resulting from use of these less invasive procedures could alleviate the need to prescribe opioids post-surgery.

Conclusion

AdvaMed appreciates the opportunity to provide these comments and urges the CDC to strongly consider them as the agency formulates additional policy and guidance in this area. We, along with our members, look forward to continuing to work with the CDC on solutions that will help to alleviate and control the acute and chronic pain that is contributing to the nation-wide opioid crisis. Please feel free to contact me should you have any questions at 202-434-7218 or ddorsey@advamed.org.

Sincerely,

DeChane Dorsey, Esq.
Vice President
Payment and Healthcare Delivery Policy

AdvaMed
Advanced Medical Technology Association

June 16, 2020

Via Electronic Mail Only
Robert R. Redfield, M.D.
Director
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Mailstop S106-9
Atlanta, GA 30329

Re: Management of Acute and Chronic Pain: Request for Comment (Docket No. CDC-2020-0029)

Dear Dr. Redfield:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments for consideration by the Centers for Disease Control and Prevention (CDC). AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings, including innovative devices, medical applications, and diagnostic tests that treat, manage, and monitor pain.

AdvaMed thanks the CDC for soliciting comments concerning perspectives on pain experiences and pain management for patients with acute and chronic pain. Though the comment solicitation sought feedback from patients, their families/caregivers, and health care providers, AdvaMed thought it was imperative for the medical device industry to also weigh in on this important issue. Medical devices are often overlooked in policy discussions regarding alternatives to opioids. For instance, the CDC Guideline for Prescribing Opioids for Chronic Pain (March 2016) refers to, and encourages use of alternatives to opioids, but provides limited direction on appropriate options for patients or providers. When referencing non-pharmacological treatments, the examples given are exercise therapy and cognitive behavioral therapy. Medical devices can and must be part of the non-opioid alternative conversation.

The opioid epidemic continues to take a tremendous toll on our country and its citizens. Given the link between opioid abuse and chronic and acute pain, significant consideration should be given to advancing care pathways that identify, address, and alleviate these types of pain, including procedures that may reduce the level of pain experienced by patients (i.e., minimally invasive procedures) and other evidence-based device interventions that can directly target and minimize acute and chronic pain, including invasive and non-invasive modalities such as spinal cord stimulators and other types of neuromodulation systems, barrier films, implantable intraspinal drug infusion pumps, cooled and standard radiofrequency neuroablation, cryoneurolysis, vertebral augmentation, electromagnetic energy, digital therapeutics, ultrasound guided regional anesthesia, and portable continuous pain relief systems.

The FDA has approved/cleared more than 200 medical device alternatives to opioids that help treat various types of pain. Despite this, the CDC's 2016 Guidance and the April 17th Request for Comment, fail to acknowledge the role of medical devices, which are used for both acute and chronic pain management and,

in some instances, are proven to reduce opioid dependence. Many of these medical devices are also considered to be reasonable and necessary and are covered by Medicare and other insurance plans.

AdvaMed is hopeful the CDC will begin to change this dynamic, and that it will do so in such a way that other federal agencies and departments take notice to align their guidelines and public communication efforts. AdvaMed encourages the CDC to be explicit in referencing the use of medical devices in future guidelines— including examples of the device types that can be used. This level of information will alert providers and patients to the presence of these medical device alternatives which may be considered as first-line alternatives to opioid use. We believe the CDC's 2016 Guideline should also be updated to instruct physicians to advise patients of the medical device alternatives to opioids available to manage pain to better enable patients and physicians to make collaborative, fully informed decisions. We also encourage the agency to provide similar guidance for managing patients with acute pain.

AdvaMed and its members are dedicated to doing our part to assist in alleviating the opioid epidemic. We encourage the CDC to partner and engage with other agencies such as the NIH, Veterans Administration, and Department of Defense to create a more comprehensive approach to addressing this crisis. We further encourage the CDC to continue to solicit input from interested stakeholders— including medical device manufacturers. Members of the medical device industry have devoted countless resources and research into the development of devices which address the needs of patients with acute and chronic pain while reducing and possibly alleviating the need for opioids. The policies underlying the consideration and use of these technologies should be evaluated in a way which makes their use a viable option for patients who are managing pain. We would like to address the following issues in our comments:

- Policies that may disincentivize use of therapies that manage chronic and acute pain and that minimize opioid abuse and misuse
- Other Options

Policies that may disincentivize use of therapies that manage chronic and acute pain and that minimize opioid abuse and misuse

AdvaMed members manufacture a variety of device-based treatments that can be used in lieu of opioids. These devices effectively manage both chronic and acute pain and may also be used to address the management of opioid addiction. The manufacturers of many of these products have developed evidence which shows a correlation between use of the devices and a reduction in the need to use and/or prescribe opioids. Despite this, many of these devices face deployment, reimbursement, and insurance coverage challenges.

Clinicians utilize a variety of devices during surgical procedures, post-surgically, and in post-acute care settings to alleviate or reduce pain symptoms. These devices which include drug-delivery devices that administer a non-systemic non-opioid analgesic directly to the site of a surgical incision, block nerve pain at the incision site, or allow minimally invasive and/or percutaneous treatment, effectively address acute and chronic pain and minimize post-procedure pain are frequently not a viable option for providers due to lack of awareness and limited coverage. We ask the CDC to implement guidelines which promote and support the use of medical devices and the ancillary procedures that facilitate their use, where such technologies have evidence of opioid reduction and/or pain alleviation.

Barriers which impede the ability of physicians and patients to gain access to the acute and chronic pain treatments that best suit their needs must be alleviated. Existing payment policies disincentivize provider use of potentially highly effective device-based pain management alternatives as a part of acute and chronic pain management strategies— making it far easier to write a prescription for potentially addictive opioids that will

be separately paid. AdvaMed recommends that the CDC partner with other agencies to resolve these payment disparities and to better allow providers who choose to deploy opioid alternative technologies in the treatment of their acute and/or chronic pain patients, especially those at risk for developing opioid use disorder (OUD), to do so without being penalized. We also support the continued tracking and production of evidence-based information by manufacturers of devices which may reduce the prescription and use of potentially addictive opioids.

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Conclusion

AdvaMed appreciates the opportunity to provide these comments and urges the CDC to strongly consider them as the agency formulates additional policy and guidance in this area. We, along with our members, look forward to continuing to work with the CDC on solutions that will help to alleviate and control the acute and chronic pain that is contributing to the nation-wide opioid crisis. Please feel free to contact me should you have any questions at 202-434-7218 or ddorsey@advamed.org.

Sincerely,

DeChane Dorsey, Esq.
Vice President
Payment and Healthcare Delivery Policy

From: Alison Jones
To: NCIPCBSC (CDC)
Subject: Written Comments on Opiod Use
Date: Monday, July 27, 2020 11:57:45 PM

To whom It May Concern:
I have read through your literature on the above and would like to comment. I suffer from chronic pain and have for several years.
Some of my dx codes are:

M43.16 Spondylolisthesis, lumbar region
M46.1 Sacroiliitis, not elsewhere classified
M62.81 Muscle weakness (generalized)
M54.18 Radiculopathy, sacral and sacrococcygeal region
Z45.2 Encounter for adjustment and management of vascular access device
Z51.81 Encounter for therapeutic drug level monitoring Mig719182-
Z79.891 Long term (current) use of opiate analgesic Mig719182-
M48.062 Spinal stenosis, lumbar region with neurogenic claudication Mig719182-
M79.18 Myalgia, other site Mig719182-
M54.2 Cervicalgia Mig719182-
M54.5 Low back pain Mig719182-
M54.6 Pain in thoracic spine Mig719182-
M62.838 Other muscle spasm Mig719182-
M96.1 Postlaminectomy syndrome, not elsewhere classified Mig719182-
R07.82 Intercostal pain Mig719182-
R29.6 Repeated falls Mig719182-
R29.898 Other symptoms and signs involving the musculoskeletal system Mig719182-
S22.000A Wedge compression fracture of unspecified thoracic vertebra, initial encounter for closed fracture Mig719182-
S22.000S Wedge compression fracture of unspecified thoracic vertebra, sequela Mig719182-
Z45.1
Encounter for adjustment and management of infusion pump Mig719182-
M47.16 Other spondylosis with myelopathy, lumbar region Mig719182-
M47.812 Spondylosis without myelopathy or radiculopathy, cervical region Mig719182-
M47.814 Spondylosis without myelopathy or radiculopathy, thoracic region Mig719182-
M47.816 Spondylosis without myelopathy or radiculopathy, lumbar region Mig719182-
M47.897 Other spondylosis, lumbosacral region Mig719182-
M47.898 Other spondylosis, sacral and sacrococcygeal region Mig719182-
M51.26 Other intervertebral disc displacement, lumbar region Mig719182-
M54.12 Radiculopathy, cervical region Mig719182-
M54.14 Radiculopathy, thoracic region Mig719182-
M54.16 Radiculopathy, lumbar region Mig719182-
M54.17 Radiculopathy, lumbosacral region Mig719182-
C50.919 Malignant neoplasm of unspecified site of unspecified female breast Mig719182-
G43.909 Migraine, unspecified, not intractable, without status migrainosus Mig719182-
G58.0 Intercostal neuropathy Mig719182-
G89.18 Other acute postprocedural pain Mig719182- G89.4
Chronic pain syndrome Mig719182-
G90.50 Complex regional pain syndrome I, unspecified Mig719182-
G90.59 Complex regional pain syndrome I of other specified site Mig719182-

M21.371 Foot drop, right foot Mig719182-
M25.9 Joint disorder, unspecified Mig719182-
M47.817 Spondylosis of lumbosacral region without myelopathy or radiculopathy
G90.521 Complex regional pain syndrome I of right lower limb
G89.28 Other chronic postprocedural pain
M54.17 Radiculopathy of lumbosacral region
R53.0 Neoplastic (malignant) related fatigue
Z91.81 History of falling
M51.16 Intervertebral disc disorders with radiculopathy, lumbar region

So as you can see, I definitely suffer from chronic pain,most all of it started after a cancer dx and txt involving chemo and radiation. I now have an implanted pain pump, but prior to the pump I had to use opioids just to have any quality of life. I had tried all of the conventional therapies, NSAIDS,ice, heat, rest, 2 yrs of physical therapy, etc. and the PT helped some, but not enough to allow me any quality of life. My pain dr, does monthly drug screening for any pt on opioids, as well as when I first started them, I was started at a lower dose and titrated up to a level that worked. I have taken percocet, morphine, dilaudid, and Xtampza. I have used both regular oral and ER forms of different medications. The ER did not serve any purpose for me as the breakthrough pain would be unbearable, so the regular oral meds always worked better for me. During the time I was taking opioids I was closely monitored, (monthly visits) and because the drugs were explained to me in great detail and I was given literature before I started them--I was always comfortable taking them, discussing issues with them with my pain dr and never worried about getting addicted or becoming dependent on them. After the pain pump was put in, (and a yr later a spinal cord stimulator) i quit taking the opiods for pain control. The pain pump has worked great. IThere is nothing that is going to get rid of my pain completely so I still deal with a lot of pain, but in addition to the pump and SCS, my dr does ketamine infusions every 4 wks, which has greatly reduced my pain level. I still periodically (usually right before the ketamine infusions) will need to take 10 mg of percocet, but it is very rare and never more than 20mg total for a couple days.

In summary, I am a firm believer that opioids do serve a major purpose for people that are suffering from chronic pain. If it hadn't been for the opioids during the time of doing the trial for the pain pump, then the surgery for permanent placement--I would've had no life whatsoever. I had already had to quit work, but was literally unable to complete the activities of daily living due to the pain. I think that if they are managed properly and the rules and expectations (both from dr and pt) are outlined and understood up front, that the opioids can really help a pt suffering from any sort of chronic pain. If I can answer any other questions, please feel free to email me back. Thanks, Alison Jones

From: Amanda Ledford
To: NCIPCBSC (CDC)
Subject: July 22 2020 comment
Date: Wednesday, July 22, 2020 1:40:02 PM

I am a chronic pain patient who has been navigating all these road blocks to my care. The doctor patient relationship has been decimated. The DEA, pharmacists, pharmacy benefit managers, insurance companies, and politicians are being allowed to make medical decisions. Any other time if someone was making practicing without a license they would be arrested and charged. Why is this being allowed?

I want to implore that this is acted upon with the utmost urgency. And I didn't hear many people discuss the fact that doctors are fearful to prescribe due to an out of control DEA. The DEA is raiding doctors offices with guns drawn, seizing all assets and prosecuting these doctors as drug dealers. There are many doctors in prison for 30 plus years for trying to help patients. Can you blame the doctors for not wanting to help us patients? People are being tortured when in reality most deaths are due to illegal fentanyl and it's analogies. I heard there would be a 12 month comment period. So what can these patients do in the meantime? Many of us have been barely hanging on the last four years. How many more suicides or bodies giving out will there be while meeting after meeting after request for comment happens? We need ACTION now. If just you get the DEA to stand down until you can get this sorted. Thank you for your time in reading this.

Sent from my iPhone

From: Desiree Lyon
To: NCIPCBSC (CDC)
Subject: porphyria pain
Date: Tuesday, July 28, 2020 5:39:04 PM

If you are a patient, please identify if you mostly experience acute or chronic pain and if you feel opioid pain medications have mostly helped you, mostly harmed you, neither, or an even mix of both

My name is Desiree Lyon. I suffer from on of the Acute Hepatic Porphyrias (AHP) called Acute intermittent porphyria (AIP) , a a rare inborn error of metabolism that is one of the most painful in human kind. Unfortunately, I had over 100 attacks and was left with severe nerve damage/neurapathies.

The acute porphyrias also are pharmacogenetic disesaes , which means there are a host of drugs porphyria patients cannot take without causing critical attacks. Among these drugs are pain medications. In fact, the only pain medications that patient can take with AHPs are opioids. Although this sounds false, this has been veryifeid with the most renown experts. It is already a commonly demeaning experience to ask for pain medication but to be classed in the opioid set is distressing . I founded the American Porphyria Foundation, was executive director for 30 years and am now global director of what is now a 13,000 member organization. Yet, when doctors find out I use opioids for severe nerve pain, they change their attitude toward me and see me as a drug seeker. They ignore the fact that pain medications enable me to work and live a normal life.

Sadly, this is not uncommon for people in constant pain. Thus, patient endure both emotion al and physical pain. My pain doctor is a neurologist at a famous cancer center. She has been with me during a bad attack and knows well my circumstances. I would like the chance to explain pain from a patient perspective and the challenges in mitigating the pain. They are far too many for a suffering person. Thank you,

Desiree Lyon
Global Director
American Porphyria Foundation
www.porphyriafoundation.org
713-857-0995 Mobile
301-347-7166 Office

From: Amy Partridge
To: NCIPCBSC (CDC)
Subject: Patient Interviews
Date: Tuesday, July 28, 2020 2:13:16 PM

Good Afternoon,

I would like to submit my name for consideration to be one of the 100 individuals interviewed by the CDC committee charged with the revision of the 2016 Guideline.

As a former health insurance executive with decades of experience in the industry, my most recent role included oversight of launching health plans for health system clients across the country who wanted to deploy an Integrated Delivery and Finance System (IDFS). With this experience, I can provide a unique perspective as a patient who had to navigate the systems I was once responsible for building. In 2016, at the age of 39, I was forced to stop working after developing intractable pain as a result of several spinal procedures and epidural steroid injections. The procedures that were meant to help me instead rendered me disabled. As a patient and advocate, I had the opportunity to speak to the FDA during a patient meeting in 2017, and was invited to participate in a patient panel during a Health and Human Services Pain Management Task Force meeting last year.

Each day, we see an increasing number of patients posting about losing access to care. I feel responsible for trying to help in any way that I can, while I can. And although I decided not to submit an application to participate on the CDC workgroup this year, it was only because my health is unpredictable and I didn't want to commit to something I wasn't sure I would be able to fully participate. However, I would very much appreciate the opportunity to be one of the 100 patients selected to speak to the workgroup about the challenges I have experienced in obtaining adequate care for my multiple chronic conditions, one of which is permanent, progressive, and has rendered me disabled with intractable pain.

Please feel free to contact me via email or phone if you have any questions, or would like more information.

Sincerely,

Amy Partridge
National Pain Advocate
412.596.0083

From: Andrea Giles
To: NCIPCBSC (CDC)
Subject: Statement from an Intractable Pain Patient unable to speak at meeting.
Date: Wednesday, July 29, 2020 12:10:04 PM

I am a 51 year old woman in Wyoming. I have been diagnosed with Spondylothesis, spondylosis, multiple herniated disks in my Cervical and Thoracic spine, severe narrowing of the spinal canal at multiple areas, multiple spinal bone spurs, Cervical and Thoracic radiculopathy that causes severe pain down through both shoulders, a constant headache, arms, ribs and back. I have severe Osteoarthritis that has effected all of my joints, from the large (hips,spine, knees, shoulders, elbows) to the small (hands, fingers, foot and toes). I have DDD, DJD. I had a spinal fusion of L4,L5,S1, which failed, in 2010. In 2011, I had 3 right hip replacements that all failed, the last one becoming infected with MRSA culminating in 52 surgeries over 4 years, ending with a total disarticulation in 2015. I now am wheelchair bound with severe phantom limb pain. I've been diagnosed with Fibromyalgia, IBSD.
I was referred to a Pain Management Physician in Montana. After signing a pain contract, he prescribed opioid medications, at a low dose, which over months he increased to 120mEq/day. I never failed a UA, pill count, used more than one pharmacy or saw any other physician. I was able to function with minimal pain, completing my ADLs, caring for my family, doing necessary household work and volunteering in my community (since after the disarticulation, I had to stop working as an ER Nurse of 15 years). Then in April of 2016, at a regular monthly appointment, my Pain Management Physician told me that due to the new CDC " guidelines" he was unable to prescribe opioids to any patients anymore. He cut me off of the opioid medications, cold turkey.and discharged me as a patient. From that day on, I have been unable to find any Pain Management Physicians, Primary Care Physician's or any Specialty Physicians in Wyoming or Montana, even looking 8 hours away from my home. My Primary Care Physician referred me to a Palliative Care Physician in 2019, who I still see monthly and who has refused to prescribe opioid medications. I now suffer with severe Osteoarthritic pain in my remaining knee, which makes transferring to/from my wheelchair excruciating and dangerous. My knee has caused me to fall multiple times causing multiple injuries. However, due to my history with MRSA, no surgeon will repair/replace my knee or do any surgical procedure on my spine. I have had 18 Epidural Steroid Injections, and nerve ablations in my knee and spine. I have been through/tried CBT, meditation, acupuncture, yoga, psycho therapy, physical therapy, aqua therapy, music therapy, virtual reality therapy, I am on antidepressants, gabapentinoids, I have tried multiple supplements. After an attempt to use NSAIDS, I developed Stevens-Johnson Syndrome Lansing in the ICU/BurnUnit for 6 weeks so I am unable to take any NSAIDS.
Since being denied opioids, I have developed severe hypertension (have to take meds), depression and cardiac arrhythmias. In 2017, I suffered 2 sudden cardiac arrests, which I survived only because my husband, also an ER Nurse was home and started CPR until the ambulance arrived. The Cardiologist found no underlying cardiac disease or reason for the arrests. He stated the constant, untreated, severe pain probably was the cause, however, STILL no physician, even my Palliative Care Physician, when Palliative Care is supposed to be exempt from them, will prescribe any opioid medications.
I have tried EVERY alternative therapy and non-narcotic pain medication, I have made myself a DNR in the hope that I will have another sudden cardiac arrest to end my suffering since I will not commit suicide if I can help it. The data shows that the Overdose Crisis is continuing to increase despite a significant decrease in opioid prescribing. Autopsy's show that illicit fentanyl and heroin/illicit drugs and poly substance abuse is the primary cause behind the

rising death toll. Yet the DEA and lawmakers are making it impossible for physicians to provide individual based treatment to their patients due to threat of prosecution and loss of their license. Thousands of chronic/intractable/Veteran pain patients have committed suicide due to severe untreated pain caused be medical abandonment. The suicide rate increases every week. It will continue if the government doesn't get out of our exam rooms and doctor's offices. "First Do No Harm" means nothing anymore. Opioid medications have proven to be safe and effective for over 100 years along with close physician monitoring and patient education. The addiction rate for legitimate patients in need of these meds is less than 3%. Why abandon and torture the 97% of the 50 million Americans who are suffering? The involvement of mainly addiction specialists, groups like PROP, SHATTERPROOF, PharmedUp and the Rummlers Hope Network, all of which are very biased and many who have members with major conflicts of interest (financially and career profiting) or who have personally suffered the deaths of loved ones who overdosed (on illicit or with poly substance drugs) who now blame physicians for their pain, which has led to these weaponized, damaging, non-fact based "guidelines " and state laws. Now the HHS task force is trying to make it the law that after spending years and thousands of dollars on alternative therapies, which have proven largely ineffective during studies, then being put on the MAT medication buprenorphine, which was not intended for chronic pain, but for OUD. Buprenorphine has been shown, in studies to be ineffective for a large number of chronic pain patients or, if effective, the effectiveness only lasts for a few weeks before becoming ineffective. It has also been shown harder to wean off of than full mu receptor opioid medications. (However, writers of theCDC "guidelines ", like Andrew Kolodney and other PROP members will profit financially from its widespread use). If the HHS Taskforce's bill proposal becomes law, chronic pain patients, which was supposedly written to help chronic pain patients access effective pain treatment, denied since the release of the CDC "guidelines ", doesn't help patients or really improve anything at all.
The amount of damage/injury caused to 50 million Americans has been widespread and severe, even deadly. So far, every so-called improvement to the CDC "guidelines " has proven to be ineffective, just the same worse written in a different format. The millions of chronic/intractable pain patients is America need your help! Not just empty words and forcing us to spend more time, Money and the risk of further damage/causing MORE pain due to botched/ineffective procedures, but the ability of Physicians to use their vast experience, education, knowledge expertise to treat patients individually, as they see fit, keeping the decision between them and their patient, without government/state law/DEA interference, allowing the patient to decide what is decide whether or not their willing to accept the pros and risks of opioid medication, with close monitoring by their physician. Law enforcement needs to focus on the illicit drug trade across our borders through our ports, the mail, etc instead of punishing law abiding, legitimate patients and their physicians.
Thank you for reading my lengthy comment. Please help is!

Sincerely.
Andrea Giles
543 East Monroe Street
Powell, WY. 82435
(307)-254-0008
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From: Annie Shoger
To: NCIPCBSC (CDC)
Subject: Comment for meeting of the NCIPCBSC
Date: Wednesday, July 22, 2020 7:25:28 PM

In 2013, the United Nations general assembly adopted a position that says under treated pain is paramount to cruel and inhumane treatment tantamount to torture. Treating pain is the most basic of human rights and patients who are under treated might as well be tortured by ISIS who then cuts your hand off.

As a person in chronic pain, I am beginning to lose all hope that my life will not return to at least a manageable quality of life. The reason is because I am unable to receive the medical care that I so desperately need, the medical care that I had been receiving for 25+ years and that had been effective in helping reduce my pain. I have severe degenerative disc disease, multi level spondylolisthesis, bilateral spondylolysis, pars defect, osteoarthritis throughout my body, bulging discs, stenosis at L5-S1, and anterolisthesis. Throughout my journey, I have tried most of the alternative medicines i.e. acupuncture, massage, chiropractic, physical therapy, inversion table, tens unit, yoga, meditation, tai chi, etc. While for the medical side, I have had multiple steroids epidural injections, trigger shots, medial branch block, radio frequency ablation and ketamine infusions . However, there are really only two things that give me any relief. One thing is opioid pain medication. How it helps is that it takes the constant debilitating pain that I suffer to a level that I am able to do things. My pain doctor has forced tapered me by 63% and has no intention of stopping. Then there are the issues with the pharmacy and the health insurance company. Why do I have to suffer needlessly when it is known that it helps. It is bad enough to have to deal with the pain itself. I did not ask for it, and you know that it could happen to anyone even you. During the time that I have been seeing doctors for my pain never did they try to push opiates. As a matter of fact, their preference was to avoid it if possible.

There is research that has found that only 4/1000 become addicted. One must have the gene that causes addiction. A study in Boston found that only 1.3% of overdose victims has had opioid prescriptions. Additionally, it is one of the safest medications on the planet which has been used for 4000 years with few side effects. If a person has been on opiates for a period of time then it is unlikely they would have respiratory depression as was explained to me in a medical report I read.

Now, I am unable to find a doctor who will prescribe the amount of opioid medication I so desperately need to live. Doctors are scared of losing their practice i.e. having the DEA come to close them down. A pharmacist can deny filling the prescription because "they don't feel comfortable filling it." There is also the problem that the distributor is now limiting the amount of opiates a pharmacy receives, another tactic by the government to fight the opioid crisis.

The other thing that I have had success with is a radio frequency ablation. However insurances require a test (medial branch block) to be performed before each radio frequency ablation. The issue is that the insurance requires the test (medial branch block) to be done each year a radio frequency is to be done. Some insurance companies even require that two of them are performed. Then there is the issue that they will only approve 3 levels and for myself I need 5 levels on both sides done. That could mean that I would have to have 5 to 6 procedures done

making it cost prohibitive.

Honesty I feel that the government has no place in the relationship between a Doctor and their patient. Their efforts should not be targeting chronic pain patients and doctors. It should be looking at the street heroin and illicit fentanyl. That is where the real problem lies.

Please give me life so that I don't have to choose death. The CDC guidelines might be fine for first time patients needing to start on an opioid prescription for the very first time but not for folks who have been on them for years because it helps them with their chronic pain to live a decent life.

Thank you for your time and serious consideration. I truly do appreciate it.

Best wishes,
Annie Shoger
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Fort Collins, CO 80521
annieshoger@gmail.com
970-214-0532

June 5, 2020

Centers for Disease Control
1600 Clifton Road NE
Mailstop S106-9
Atlanta, GA 30329
Attn: Shannon Lee

Re: Management of Acute and Chronic Pain, Docket No. CDC-2020-0029

Dear Injury Center Leadership,

By way introduction, my name is Dr. Thomas Smith and I am the Chief Medical Officer of BioDelivery Sciences International, Inc (BDSI). We are a company dedicated to driving innovative solutions for the treatment of serious and debilitating chronic conditions. We work to advance therapies designed to give individuals living with chronic conditions the opportunity to make the most of their lives. I write to offer our company's recommendations related to pain and pain management. This letter will focus specifically on the use of and prescribing of medications for the treatment of chronic pain.

BDSI is aware that the CDC's *Guideline for Prescribing Opioids for Chronic Pain*, most recently updated in 2016, is under consideration for potential update and revision. The company is also aware that those revisions will offer the opportunity for review and public comment. In advance, BDSI hopes to offer a series of initial considerations.

1. **Distinguishing between Schedule II and Schedule III medications is important to the reduction of addiction risk in patients.**

   BDSI understands that the current *Guideline* does not distinguish between Schedule III and Schedule II opioids. We encourage the CDC to prioritize the reduction of addiction risk by recommending prescribers consider a Schedule III analgesic before a Schedule II.[1] The CDC currently recommends starting opioid therapy with immediate release Schedule II opioids, which have been shown to have higher rates of addiction and abuse before considering a Schedule III.[2]

2. **Schedule III non-traditional opioids face significant nonscientific obstacles leading to underutilization of safe, effective, and sustainable options for care.**

   Schedule III analgesics, such as buprenorphine, are often the subject of persistent myths regarding its pharmacology and efficacy for pain in comparison to traditional opioids; these myths are especially prevalent with the confusion about the distinct FDA indication for the treatment of

[1] Pain Management Best Practices Inter-Agency Task Force Report. 2019 May.
https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf
[2] U.S. Department of Health and Human Services Report. October 2019.
https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf

chronic pain[3] versus opioid dependence[4] and the lack of understanding that buprenorphine can be prescribed without an X-waiver[5] for chronic pain. The majority of medical providers are not aware that a waiver is only necessary when treating opioid use disorder/addiction.

These unfortunate nonscientific obstacles have led to an ongoing underutilization of a safe, effective, and sustainable management option for patients on chronic opioid therapy but may be experiencing other unintended negative consequences of high-dose opioid use, such as development of tolerance and hyperalgesia[6], and/or impairments in mood, cognition, sleep, and other aspects of function.[7]

3. **Nonopioid therapies remain a viable choice, but medical histories of patients particularly with renal and GI complications often demand opioid alternatives with both unique safety profiles and a relative minimum of drug-drug interactions.**

   Nonpharmacologic therapy[8] and nonopioid pharmacologic therapy remain a viable and preferred choice for chronic pain. However, medical history and potential benefit and harm should be individually assessed[9]. There is considerable evidence that NSAID-related CV, renal and GI complications place a substantial clinical and economic burden on the healthcare[10], particularly among elderly.[11]

   As the number of elderly individuals with chronic pain increases in the US, buprenorphine's unique safety profile and relative minimum of drug-drug interactions[12] will make it particularly attractive to in this population. Buprenorphine and its metabolites are excreted mainly by the biliary system, making buprenorphine more suitable for patients with renal and hepatic impairment than full mu-opioid receptor agonists.[13] Buprenorphine is not likely to cause clinically important interactions with other drugs metabolized by major hepatic CYP450 enzymes. This translates to fewer drug–drug interactions, potentially diminishing adverse events when combining buprenorphine with one or more agents affecting CYP metabolism.[14] Buprenorphine has little to no immunosuppressive effect and appears less likely to suppress the gonadal axis or testosterone levels.[15] It is considered a preferred opioid option[16] for patients with either renal or hepatic disease.[17]

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[3] Gudin J & Fudin J. Pain Ther. 2020 Jan 28. doi: 10.1007/s40122-019-00143-6. [Epub ahead of print].
[4] Khanna IK & Pillarisetti. S. J Pain Res. 2015; 8:859-70.
[5] Fishman MA, et al. Pain Med. 2019 Nov 7. doi: 10.1093/pm/pnz197. [Epub ahead of print].
[6] Pergolizzi JV & Raffa RB. Journal of Pain Research 2019:12 3299–331.
[7] Rudolf GD. Phys Med Rehabil Clin N Am. 2020; 31:195-204.
[8] Chang KL, et al. FP Essent. 2015 May; 432:21-6.
[9] Centers for Disease Control. Guideline for Prescribing Opioids for Chronic Pain. 2016.
[10] Marcum ZA & Hanlon JT. Ann Long-term Care. 2010; 18(9): 24–27.
[11] Fine M. Am J Manag Care. 2013;19(16 suppl): 267-S272.
[12] Pergolizzi JV, et al. Pain Pract. 2010;10(5):428-450.
[13] Gudin, 2020.
[14] Ibid.
[15] Davis MP. J Support Oncol. 2012;10(6):209-19.
[16] Pergolizzi, 2019.
[17] Kress MK. J Opioid Manag. 2019 Nov.

Contrary to fears of blunted effect and precipitated withdrawal, continuing use of buprenorphine as a baseline agent combined with another opioid has been shown in a multitude of studies to be safe and effective for analgesia. Because therapeutic doses of buprenorphine do not occupy 100% of available opioid receptors, unoccupied receptor availability can allow patients to achieve pain relief in varying degrees if a full opioid[18] agonist is added to buprenorphine.[19]

4. **In considering the complexity of pharmacology, risk, and benefit of pharmacological therapy, when medically warranted, clinicians should consider agents with reduced potential for respiratory depression and relatively lower risk of abuse and addiction.[20]**

   In prescribing buprenorphine for both acute as well as chronic pain, physicians are relieved of the ever-present anxiety that treatment can lead to respiratory depression or death.[21]

   In a phase I placebo-controlled trial on respiratory drive (ventilatory response to hypercapnia), buprenorphine buccal film did not reduce respiratory drive at any dose in healthy volunteers, including the maximum available prescription dose of 900 µg. In contrast, oxycodone resulted in a dose-dependent decrease in respiratory drive; and the reduction in respiratory drive with oxycodone 60 mg was statistically significant relative to placebo and buprenorphine.[22]

   In considering the complexity of pharmacology, risk, and benefit of pharmacological therapy, when medically warranted, clinicians should consider agents with reduced potential for respiratory depression[23] and relatively lower risk of abuse and addiction. One agreed-upon approach by HHS[24] and the prescribing community to improving the management of pain is the preferential use of potentially safer analgesics as described above.[25]

5. **The Department of Health and Human Services (HHS), in its recently released guide for tapering opioids, calls for a great role in promoting buprenorphine as an alternative pain management options for patients "on high opioid dosages unable to taper despite worsening pain and/or functioning with opioids, whether or not OUD criteria are met."[26]**

   The recent Inter-Agency task force report specifically considered alternatives for pain management. The report highlighted the scientific evidence cited in this letter indicating that when opioids are started, clinicians should prescribe the lowest effective dosage and carefully reassess evidence of individual benefits and risks when morphine milligram equivalents/day increases with higher dosages. We would also highlight that primary use of buprenorphine, rather than use only after

[18] Rauck RL, et al. 2016;128(1):1-11.
[19] Hale M et al. J Pain Res. 2017;10:233-240
[20] Dahan A et al. Br J Anaesth. 2006; 96(5):627-632.
[21] Kress, 2019.
[22] Webster L, et al. Scientific Poster Presented at AAPM Annual Conference, 2020.
[23] Dahan.
[24] HHS, 2019.
[25] Hale, 2017.
[26] HHS, 2019.

failure of standard mu agonist opioids such as hydrocodone or fentanyl, if clinically indicated, should be considered.[27]

In summary, BDSI is committed to working with the CDC to help prescribers make pain management decisions. Historically, the fail-first practice favoring Schedule II opioids has led to a higher risk of addiction for patients with chronic pain. **BDSI recommends a harmonization of the Inter-Agency Task Force report with future CDC outputs in order to clarify the alternative options available for patients**. We believe that a consideration of the safety, efficacy, and underutilization of Schedule III analgesics will lead to reforms in pain management that will also serve as solutions to the American opioid crisis.

Please do not hesitate to contact me to discuss this further. We look forward to hearing from you.

Sincerely,

Thomas Smith, MD
Chief Medical Officer
BioDelivery Sciences, Inc.
tsmith@bdsi.com
919-582-0195

[27] Davis, 2012.

From: Larson-Steckler, Elizabeth A.
To: NCIPCBSC (CDC)
Subject: Comment
Date: Tuesday, July 28, 2020 2:50:40 PM
Attachments: image001.png

Good Morning,

I would like to add my comments as I was not able to speak yesterday. First, I truly do appreciate the committees inclusion of patients and caregivers. I am the wife and mother of family members that have/had hereditary pancreatitis. My husband's hereditary pancreatitis led to pancreas cancer. He died due to complications of treatment. My two children diagnosed at age 1 and 2 have both struggled with this disease. They both underwent auto islet transplant total pancreatomy and splenectomy. Both had multiple complications and were left with many issues; chronic pain, malabsorption, GI issues, diabetes, dysautonomia, heart issues, malnutrition among various other issues. Currently, they are 18 and 21.

As a parent, I have attempted to find appropriate care for my kids to address their pain. I do not like the fact that they are on opioid pain meds for many reasons. The current climate has caused a great deal of harm for both my kids. They have been labeled 'addicted' by physicians who do not look at entire picture. For example I have been concerned about their malabsorption of medications and no one has taken a close look at this. I know their meds work some times and other do not. Example, my daughter was in hospital and urine test was given. It came up negative for opioids. Based on this they labeled her 'addicted', removed meds from her (no titration) and had a social worker called into talk to her about treatment. I was out of town at time, only parent. Fortunately her therapist intervened and filed a report. She was given opioids and took another test. Came back negative. The trauma they have faced by not being believed by physicians has taken a toll. Once they were labeled it has been so difficult to receive necessary care.

I believe in an interdisciplinary approach as well as implementing a multimodal approach. This has been difficult to ascertain. I have had to reach into my pocket and pay for other treatments not covered by insurance. I also enrolled my kids into a renowned pain program. I find the program we went to very traumatic. There was no options to stay on pain medication, just application of other modalities. They also wanted to take my kids off a whole host of other medications for their GI issues. They ignored my daughters concerns. Told me it was common for kids to increase their complaints while in program. I ignored her, following the rules. She ended up in hospital with thrush. I agree with the implementation of various tools and treatments. I was excited to be able to access these tools for my kids but how it was done was shaming and blaming. I do believe that my kids could have stepped down a bit on opioids with other tools and treatments but it was not allowed. Care should be individualized.

I am not only a parent but I am also one of the founders of the Foundation of Childhood Pancreatitis as well as founder of Navigations, which assists parents and caregivers with navigating care of children with chronic and complex health issues. I receive numerous calls from parents and caregivers many in regards to treatment of pain. The stories are horrific in such violation of 'do no harm'. One child was in flare. Parents had brought her into ER. She was admitted. Medical team

used lavender oil to assist with pain. I don't have any issue with using supportive techniques but that is the only thing that was provided. Another youth was left screaming in pain after an ERCP. Both physician and nurse indicated that she should not have pain and provided nothing. The nurse indicated to the mother that the child was struggling with addiction issues. I assisted this mother to get her child airlifted to another facility. It was found that the physician, when doing ERCP had gone into the pancreas NOT bile duct. This young woman received care and has since turned 18. She does not trust medical system or physicians. Her illness dictates that she does need care but due to experience and the trauma involved she does not go in regularly but ends up in crisis. Many youth are ending up being treated by psychologists. One ended up in pysch hospital. Fortunately she had attack while there and was rushed to ER where the physician finally diagnosed as hereditary pancreatitis. How traumatizing not only for youth but for parents.

In order for these youth to engage in care, they need to be respected and not traumatized. The system is creating 'noncompliant', 'difficult' patients but they do not see their role. For me the issue is just not access to opioids but better, research, earlier care, more competent care, individualized care as well as the ability to access various treatments and tools. I have witnessed both my kids at multiple times wishing they were dead because of health issues, pain and the bias in stigma currently inundating the medical field regarding opioids.

Kids with pain should be immediately referred to a pain specialist. Research has demonstrated that it is critical, if not addressed will lead to chronic pain and as I have witnessed trauma. Sadly, there is not a lot of places that truly know how to address pain. There are pockets but for many unable to reach due to many barriers. They only thing that has given them a bit of quality of life is opioids. Last year, the pain physician that my son trusted. That treated his dad, was told by his organization to cut off all individuals on pain medications. They had received a letter from our state CMS to titrate all individuals to 90MME (which my understanding was not if it was a pain physician) this was pushed federally by CMS. No referrals were provided to those being titrated. I was fortunate knowing my son's rights and was the only one to get a referral. However great damage was done. My son trusted his pain doctor. He sat and cried for days about having trusted this doctor and the doctor no longer cared about him. Most people on LTOT, have tried many things. As I said, I want other options. My kids should have received pain care early on in a compassionate way. The current climate you are suspect if you utilize pain meds. My kids are 18 and 21 and have really been harmed by physicians who have ignored their pain or indicated it was psychological. I do believe that their pain can be impacted by mood as well as mood impact pain – definitely believe this but to have physicians ignore and dismiss and rely only on psychological tools is not helpful for those with chronic pain.

Truly wish there was other options. My kids should have had pain addressed earlier in their journey. I actually advocated for that as well as a pain psychologist but their transplant team only had one visit done with them. That is not effective. Shame and blame should not be utilized or allowed at many of these pain facilities. All individuals should have access to multimodalities of care inclusive of pain medications. Through our journey pain physicians and other doctors pushed other types of care on my kids. Both underwent blocks – which they should not have due to their islet transplant. They came out worse. My daughter who only had stomach pain, now has back pain. Islets were destroyed all in attempts to remove them from opioids.

Thank you
Elizabeth Larson-Steckler

NORTH DAKOTA DEPARTMENT OF PUBLIC INSTRUCTION

Beth Larson-Steckler
Office of Educational Equity & Support
Program Administrator
701-328-3544
600 E. Boulevard Ave., Dept. 201
Bismarck, ND 58505-0440

From: Betty Acosta
To: NCIPCBSC (CDC)
Date: Wednesday, July 29, 2020 8:28:38 PM

I was operated on to remove a tumor from my spine.but during the operation they discovered that the tumor had destroyed some of my disks so they put a cage around my spine and screwed a flat metal plate into my back to attach the cage too.or whatever they call it.i also had a fusion.after the operation I hurt worse than before surgery.i have had nothing but 24/7 pain ever since.my Dr of 20 yrs tried different pain meds but they were all too strong or made me sick.i had never taken them before.i played softball for 25 yrs and wouldn't even take aspirin.he finally found a drug that I could tolerate and it took all my pain away.hydrocone/apap..since then my Dr of 20 yrs retired and I had to see another Dr in my network and the 1st thing he told me was I'm not treating any pain patients even though they billed as pain management.and the 1st discussion we had he talked to me like I was a criminal.i am 63 yrs old have never been in trouble married to same man for 40 yrs.and he talked to me like I was a drug addict and a criminal
He dispiced me and I could tell.after 2 months he took all my meds away with no warning he also took my sleep meds away at same time..I have extreme anxiety since my 2 yr old granddaughter was kidnapped and ripped out of my arms then I stopped keeping because the nightmares were so extreme and I developed insomnia my Dr said it was the worse case of insomnia he had ever seen.when new Dr took all my meds away I hadn't slept in 15 days and ended up in hospital when I had a stroke and my heart stopped.i still cant sleep and I cant find another Dr and I need surgery on the arteries in back of my head cuz they are completely blocked and I need heart surgery so my heart dont keep stopping.and I cant get my surgery because I got in arguement with the new Dr about my treatment plan or lack of one if you will.my old Dr and I had a treatment plan in place and he was supposed to follow it but he refused..so he sent me a letter cancelling me as a patient said I was a problem patient and a pill seeker because I disagreed with his new treatment plan of no treatment.i lost my life that day.i had to give up volunteering at nursing home to read bible to the patients who could no longer see well enough to read and I had to give up foster care cuz I could no longer take care of myself much less anyone else.it broke my heart.i also had to give up my grandchildren which I usually had 6. Days a week.they were my whole life.no longer can play with them or watch them so I hardly ever get to see them cuz both parents work..and only have time to go home cook homework baths and bed..I no longer have anything that resembles a life.i lay in a fetal position on couch or bed crying or screaming cuz the pain gets sooo severe and I get no break from it by sleep anymore so pain is 24/7..and I want to kill myself cuz my life is gone and the only thing left is pain.the only people you hurt by your ruling is chronic pain sufferers.no one else cuz drug dealers have the cartel and will always get their drugs.drug addicts all have dealers and know where to get their drugs but senior citizens like me dont know drug dealers so we are the only ones you hurt with your ruling.i lived my whole life responsibly and now through no fault of mine I am being punished for a drug dealers actions or a drug addicts actions j am neither just someone who suffers so much I want to blow my brains out like alot of chronic pain sufferers are doing now

Fasting growing group of suicides now cuz you can only take sooo much pain before the screaming in your head drives you crazy.and yes...pain can scream.it screams in my head constantly.i do not deserve to have my whole life taken away for someone else's actions when I am a responsible adult.that Dr.was sooo spiteful when he took my meds away he also refused to refill my blood thinner I had because of 8 strokes...I'm going to die in pain by my own hands like thousands of others are doing and my blood as well as theirs will be on your

hands.pleasd change this ruling so that we dont suffer for so.eone elses crimes or actions.please give my life back please

From:	Beverly Minich
To:	NCIPCBSC (CDC)
Subject:	2016 Guideline / AMA Recommendations
Date:	Tuesday, July 28, 2020 11:59:47 AM

Thank you for allowing me to tell you how your 2016 Guidelines took away my life. I went from an 85% functional person to a cripple with a cane that can barely walk, and will be using a wheelchair soon, if we can make the house handicap accessible. I'm 57 and otherwise healthy. When I had my pain meds, I was able to function, ADL's greatly improved as was my quality of life. None of that is possible now, of no fault of my own. Alcohol and cigarettes kill many more people than prescription pain meds when taken as prescribed and are locked up so nobody else could get them. Alcohol and cigarettes are fine but the disabled is denied lifesaving medications. How can that be? The letter you got from the AMA says we (legacy patients) should NEVER have had these medications taken away from us. We were steady. We could enjoy life, not hate waking in the morning.

I was abandoned by the medical community when the DEA got my 82 year old Pain Mgmt Doctor of 12+ years. The place I go to now, the ONLY place I could find that would take me, FORCES me to have expensive, painful procedures, knowing they're only temporary IF they help at all. One leg is about an inch longer than the other and I'm afraid I'm going to trip and fall down again. I lose my balance too often. Serious pain is all consuming. I have no ROM in my neck because of three Cervical surgeries and the hardware inside. It's hard to look around as I walk with my cane.

I'm called a "complex case" and "a mess" by doctors. I don't want to be disabled, and when I was ethically treated, I was able to do so much more. I don't drive much, as I don't want my pain to consume me to the point of hitting another car. I used to exercise several times a week but not at all without my pain controlled. I'm gaining weight, not being able to walk or exercise at all. I'd been able to keep my weight in check until I had my effective dosages of narcotic pain meds. My journey has been over 17 years and I was ALWAYS told not to let my pain get too bad. Now it's ALWAYS bad.

Please get rid of the CDC Guideline and return medical CARE to our Doctors. This is against our Eighth Amendment Right against Cruel and Unusual Punishment. It's unimaginable that, in the USA, millions of disabled have had our lifesaving medications taken away by guidelines written by ADDICTION SPECIALISTS!! We're not addicts. The addiction rate hasn't changed for decades! The OD's and deaths are from mostly illicit heroin and fentanyl. Get rid of the guidelines and give us our lives back. How can you be so cruel, to allow people with incurable painful illnesses to suffer 24/7/365?? Please give us our Doctors back and allow us to have the Doctor/Patient restored.

Thank you for your time and consideration of my pleas for my semi-normal life to be reinstated and the medications used for pain for centuries will be given back to the disabled.

Warm regards,
Bev Minich

From: Brian Zbikowski
To: NCIPCBSC (CDC)
Subject: CDC GUIDELINES CAUSED ME MAJOR DAMAGE.
Date: Wednesday, July 22, 2020 3:34:02 PM

Worked 40 years Nationally.
Last 25 years hurt no ins.
2003 Chiropractor told me I'm disabled.
2008 Became Homeless
2009 moved to Michigan bought A cheap house.Grew MJ for some releif.
Wife was SSI bipolar.
2011 Filed disability 2009 unemployment ran out looked for work for 2 years hurt.
No One would hire me.
2011 Wife left for I couldn't care give and provide her, her needs no more.
Feb-2012 paid cash for MRI
2017 took A Plea deal for SSI.
Went to A Pain Management doctor who is still my pain doctor today 7-22-2020.
He looked at MRI and told me I'm disabled.
Feb-2012 built A Doctor/ Patient relationship with MJ/ low dose opioids.
He found out I had major anxiety too.
He tryed shots, and it did nothing so he put me on 40 MME Norcos/ with low dose xanax.
Tryed mussel relaxers first.
By June-2012 he had me balanced on 40mme with 1mg of xanax and I was allowed to go to 60mme if 20 day visits.
I ALSO got A primary medicaid doctor in 2012. They offered injections only.
I also went to A neurosurgeon at Allegiance Jackson, Michigan.
He offered injections and Methadone.
I ask my pain doctor should I take Methadone, he said No not for your condition.
Also got chest scan Black Lungs.
2014 dentist says all my teeth need pulled.
Had A kidney stone and they said they will repeat (KEEP YOUR STRESS LEVEL DOWN)
Went in to get pulled but had chest pain.
Sent to U of M for Nuke stress test.
Cleared however was trying to quit cigs first.
They said they was worried about my heart.
The nuke test actually caused more chest pain.I told them to Stop during and they said they was almost done.
By 2015 I was doing OK.
HAD QAULITY OF LIFE.

THEN THE CDC INTERFERED
2015 no longer allowed 60mme.
P.T caused pain to radiate down leg when they bent my foot past my neck to stretch femer.
2017 xanax gone right when I was quiting smoking.(down to 10 A day first time in 46 years)
I could no longer go near needles without xanax so all bloodwork, flu shots Stopped.
My sleep got disrupted and stress went through the roof. Started chain smoking again. Tryed kolodapin/ seroquil/ect.
JULY 2019 minus 10 pills.
AUGUST 2019 Walmart Pharmacist shook my Norcos at me and (said her husband quit these you can too.)

OCTOBER-2019 NORCOS got weak and bloated me. Called FDA and complained.
June -2020 got new brand Norcos.
Bloating went away instantly, however they are weaker than ever.
So here we are I'm now not sleeping, just about paralized.Struggling to do my chores. Going to Store is very difficult and unsafe driving in pain with foot swelled and numb.
Barely enough medication so I don't scream now.

THANKYOU CDC GUIDLINES FOR PUTTING ME TO MY GRAVE.

THANK YOU CONCERNED POLITICIANS FOR INTERFERING WITH MY DOCTOR / PATIENT RELATIONSHIP.

CDC JUNE 22, 2020 COMMENTS

I have been a long-term chronic pain patient for over two decades, and the use of opioid medications for 22-years has been imperative, and only prescribed by my pain management physician. My name is Fred Brown, a patient, and an Advocate for Pain Patient Rights. I have brief comments that I would like to share with you; why you need to change the **Opioid Guidelines from 2016.**

I believe such added stress has been brought about due to the **Guidelines.** Many of the patients that have been injured are no longer with us, as they could not obtain their legally prescribed medications, and because of this, they began to find street drugs to relieve their pain; **or worse yet, used suicide to stop their suffering.**

We, as chronic pain patients, did not ask to be in this position, and each one of us has a **different story to tell**. I have gone through four cervical surgeries, which have **not** been able to correct the problems and have brought far more severe pain to me.

When the Guidelines in 2016 were being developed, why was it done without having at least one Pain Management physician as part of your Group? Further, my understanding is that much of this was handled in an incredibly quiet and with respect in a deceitful manner.

If pain can be relieved, why isn't it? **Why must patients** have to put up with such negativity when all that we want is to find a better quality of life. I agree that drugs such as opioids might not be needed for every pain patient. However, many of us find reduction of symptoms with the use of opioids, and in many cases, at a much higher dose than the 90MME level.

I believe that one who lives in chronic pain should also use other modalities with the pain medications, which can help them within their limitations.

I would appreciate your considering my comments from today. Thank you.

AdvaMed
Advanced Medical Technology Association

July 28, 2020

Via Electronic Mail Only
Gwendolyn H. Cattledge, Ph.D., M.S.E.H.
Deputy Associate Director for Science
NCIPC
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mail Stop S106-9
Atlanta, GA 30341

Re: Comments on the July 22, 2020 Meeting of the Board of Scientific Counselors NCIPC Opioid Workgroup

Dear Dr. Cattledge:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments for consideration by the Centers for Disease Control and Prevention (CDC) Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC,NCIPC). AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings, including innovative devices, medical applications, and diagnostic tests that treat, manage, and monitor pain.

AdvaMed thanks the BSC,NCIPC for hosting its recent meeting and for updating stakeholders on the efforts of the Opioid Workgroup. We also appreciate the BSC,NCIPC for soliciting post-meeting comments regarding the information communicated during the July 22nd meeting.

During the public comment portion of the meeting, several speakers commented on the impact of medical devices in the treatment of their pain conditions. AdvaMed strongly supports the sentiments communicated in those comments. We were very encouraged by the comments as medical devices are often overlooked in policy discussions regarding alternatives to opioids. More importantly, we were pleased to hear of the successful outcomes, health, and life improvements that these devices have brought to the patients who use them.

Medical devices can and must be part of the non-opioid alternative conversation. The FDA has approved/cleared more than 200 medical device alternatives to opioids that help treat or manage various types of pain. Despite this, the CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain fails to acknowledge the role of medical devices, which are used for both acute and chronic pain management and, in some instances, are proven to reduce opioid dependence. Many of these medical devices are also considered to be reasonable and necessary and are covered by Medicare and other insurance plans.

As the BSC,NCIPC continues to move forward with its Opioid Workgroup efforts, including revisions to the 2016 guidance and policy recommendations for the treatment of chronic and acute pain, we are hopeful that the benefits and role of medical devices as a treatment alternative to opioids are strongly considered.

Please find attached to these comments a letter that was sent to CDC Director Redfield in June of this year. We are hopeful that the BCS,NCIPC will consider many of the recommendations included in this letter, as well as the one sent to Dr. Redfield. Moreover, we look forward to continuing to engage with the BSC,NCIPC as you all continue your work in this area.

Conclusion

AdvaMed appreciates the opportunity to provide these comments and urges the BSC,NCIPC to strongly consider them as the group formulates additional policy and guidance in this area. We, along with our members, look forward to continuing to work with the CDC and the BSC,NCIPC on solutions that will help to alleviate and control the acute and chronic pain that is contributing to the nation-wide opioid crisis. Please feel free to contact me should you have any questions at 202-434-7218 or ddorsey@advamed.org.

Sincerely,

DeChane Dorsey, Esq.
Vice President
Payment and Healthcare Delivery Policy

Enclosure

AdvaMed
Advanced Medical Technology Association

July 28, 2020

Via Electronic Mail Only
Gwendolyn H. Cattledge, Ph.D., M.S.E.H.
Deputy Associate Director for Science
NCIPC
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mail Stop S106-9
Atlanta, GA 30341

Re: Comments on the July 22, 2020 Meeting of the Board of Scientific Counselors NCIPC Opioid Workgroup

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Sincerely,

DeChane Dorsey, Esq.
Vice President
Payment and Healthcare Delivery Policy

Enclosure

From: utpaindoc@aol.com
To: NCIPCBSC (CDC)
Cc: SBudoff@psadocs.com
Subject: Chronic pain patients and Appropriate Opioid Use and Avoidance Protocols
Date: Tuesday, July 28, 2020 11:25:52 PM

Good evening,

I am a pain specialist in San Antonio Texas. My name is C. William Murphy MD. I am a pharmacist, an anesthesiologist, and a pain specialist, double boarded in both. I have practiced for 35 years and have evolved with the care of chronic pain patients for that time. I have seen the evolution of pain management as a specialty and have seen the pros and cons of the use of opioid medication for the treatment of chronic pain. There are many other treatments which can be used for patients now than when I first started.

As a practicing, Board Certified Pain physician, I write today to encourage the Opioid Workgroup and the Board of Scientific Counselors, National Center for Injury Prevention and Control to include the following key recommendations in any forthcoming CDC guidelines and educational materials for pain management:

- Adopt well-researched interventional pain guidelines – Evidence-based pain interventional therapies can and must play a larger role in effective pain management and efforts to reduce opioid related harms. A thorough data analysis will demonstrate robust clinical evidence supporting interventional therapies ability to reduce pain, improve function and reduce oral medications.

- Expand CDC educational materials for non-opioid treatments – Updated patient and clinician resources are necessary to improve awareness and utilization of proven alternative therapies, especially FDA approved treatments and technologies.

- Encourage earlier patient referrals to pain specialists – Currently, specialists are often not involved early enough in diagnosing and treating pain syndromes, which can lead to suboptimal patient outcomes.

I hope this helps. I would be happy to be interviewed as a provider of chronic pain care and as a practicing pain specialist for 35 years. My email is utpaindoc@aol.com and my cell phone is 210-269-8400.

Sincerely, C. William Murphy MD

From:	Candi1767 P.
To:	NCIPCBSC (CDC)
Subject:	Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC/NCIPC) - Meeting, July 22, 2020
Date:	Tuesday, July 28, 2020 1:54:00 PM

I keep trying to send this to the address you have written in your message, but I keep getting a message back, saying it can't be delivered.
I'm going to try again & hope it goes through. Thanks!

I am writing in because I think the 2016 CDC's guidelines should be taken down & thrown away! Its all based on misinformation & all one sided. The guidelines are hurting more & more people every day(as opposed to helping). Addiction & people using illegal street drugs keep rising higher & higher, despite doctors fearing for their license, cutting & dropping people in pain from their pain meds that have tremendously helped for years. Showing that the doctors prescribing pain meds is NOT the problem for addiction or illegal street drugs. Those people wanted to do drugs(not use them for pain relief). If someone wants to get high or do drugs, they're going to(they'll find a way, one way or another & blame it on whatever). Whether a doctor prescribes or not. In fact, they'd probably be better off taking prescription pain meds since their safer & controlled(then going to illegal street drugs, laced with who knows what) & then overdosing or dying.
But now because of the cuts & drops to safe & effective prescription pain medicines, its pushing more & more to illegal street drugs, causing more & more over doses & deaths. Its causing more & more to commit suicide or have other adverse & detrimental health conditions because of all of the stress from the pain. People just can't live with SOOO much pain. & especially when there is something out there that greatly helps, it shouldn't be taken away from us.
The mass majority(90 some percent) take them responsibly & as prescribed because it greatly helps them(even in higher doses). & you can't make everyone take the same dose(or put a limit on it) because everyone is different & needs different doses, just as different medications. You cannot push a button & fix everyone. Everyone needs something different to help them(including different doses). Our bodies are all different.
Most older(over 40) that take rx pain meds, take them as prescribed & have NO problems but great benefits. The majority of addiction are younger people & they are the ones who abuse them &/or take illegal street drugs. They didn't get addicted to 1 prescription of pain meds for a week or 2. They are using that as an excuse because they wanted to do drugs & do something stronger to get a better high, so they went to illegal street drugs.
Please stop punishing & torturing people in pain by cutting the one thing that actually helps million & millions of them, to be able to get up out of bed & move through the day.
Please, Please, Please take down & throw away the 2016 CDC's prescribing guidelines. & stop putting restrictions on the doctors who are trying to help people. You are pushing more & more doctors out of their practices(who just want to help people) because they are SO afraid of the DEA coming after them & taking their license(just for trying to help people).
This has to STOP!!! NOW!!!
Thank you!
Candi

From: chavezmarth@msn.com
To: NCIPCBSC (CDC)
Subject: Untreated Pain
Date: Wednesday, July 22, 2020 6:54:42 PM

To Whom it May Concern:

It was early March of this year that I began having mild back pain that later turned intolerable within a span of 3 weeks. After calling my primary care physician, I was referred to the Kaiser Spine Center. I was prescribed ibuprofen and tylenol, topical lidocaine and was given a regimen of physical therapy exercises to do at home. After two weeks into this regime I saw no improvement and the medication made me feel sick (I was told to take the maximum amount allowed for each medication). The pain became so severe I went to the ER where I had an MRI done.

From: chris jolley
To: NCIPCBSC (CDC)
Subject: CDC comment
Date: Tuesday, July 28, 2020 2:51:29 PM

Thank you for letting me know I sent it to the wrong email. My comment is with information I'd like to know from the CDC and my story is at the end.

CDC Comment

Most of them responded that your guidelines would badly damage the chronic pain community. Even the FDA was nervous about them and asked for public comments and they said the same thing but you released them as is 4-2016 knowing what would happen to us. And that is exactly what happened to millions of chronic pain patients and their doctors.
You knew when you released the the overdose numbers you had no data to back up your numbers. The numbers were early released as a guess, an estimate. You knew your numbers were wrong by 2017 after you reviewed the death certificates. Your 63,632 number was way off. Only 42,000 out of the amount involved any opioid. 17,087 involved a prescription medication and usually had 1-2
You released a corrected report saying you had inflated the number of overdose deaths related to prescription pain medication by 53%. Why was this so quiet? Why was no one told?
The same thing happened in 2017 and 2018 and you did nothing. You did nothing. You left millions of us unable to have any quality of life. We lost jobs our homes and are now bed ridden. You are responsible for every suicide because patients were cut off the medication that we needed to live. You Arrested our doctor for treating us. You terrorized-us, our doctors and pharmacist with your nazi style DEA agents. Your personal attack dog Sessions.
Then in 2019 4 years later you to admit your guidelines were misleading, misinformed and were dangerous to force taper or cut off pain medication to any patient. And so much more.
With all of this that happened you are doing a rewrite of the guidelines is great for new patients and new doctors but what about the ones who went through this? Will you get our doctors out of jail or tell the doctors to give us back our pain medication?
WHAT WILL YOU DO FOR US???

My name is Chris Jolley I'm 63 and live in West Jordan Utah. I've been a

chronic pain patient for over 30 years and in pain management sense 1999.
I have a son and daughter and 3 grandkids.

I was with my pain doctor for 20 years at the same clinic and on the same dosage when on 4-23-16 the medication that controlled my pain was stopped. I arrived for routine follow-up when a new doctor I had never seen walked in to tell me he is stopping all pain medication for each person within one month. They released me as a patient.

I have Spinal Bifida, Scoliosis, Fibromyalgia, chronic kidney stones and more. My worst pain is from migraines, including chronic cluster migraines, several ruptured disks from a back injury and severe disk degeneration and chronic kidney stones.

After that doctor at the clinic abandon me took me six months to find a clinic to accept me as a patient and I was treated as a new patient.

On 8-23-2018 I was having one of the worst cluster migraines On it's 5th day, I had a flare up from my disk rupture, and my chronic kidney stones started dropping. This was my 4th kidney stone episode this year. I was in horrific pain.

I have a pain contract so my son called the clinic to let them know he was taking me to the ER. He was told he could take me but under no circumstances could they give me any pain medication. My son called 3 more times; on the 3rd call was told we needed permission from the doctor, and he had already left for the day. The next day my son was told the same and the next appointment we were told the same. The ER could not treat my pain.

Pain patients have a disability and because of that disability we suffer discrimination. Dr. abandoned us pharmacies profile us to choose if they will fill the prescription. The public treats us like scum.
A family pet would never be allowed to live in pain. The family would show mercy and let the pet go to sleep.

Before April 2017, I was happy, able to work, involved in many craft projects and saw my daughter and grandchildren often and they live 40 miles away. Because of the migraines my husband created a dark room and I spend most of my time in there. My back and other causes make me change positions

every hour. I do not get much sleep. After months of appointments I said to that doctor I think about suicide every day sometimes every hour because of the pain. He did not even look at me and walked out the door.

This doctor was fired for what he did to me, and the doctor who took over started to give me my pain medication back and I was shocked by this. I'm almost back to 100%.

I got my meds back now I had to find a pharmacist to agree to fill it. I was able to fill it at my local pharmacy but it was $160.00 for each box and I get 5 of them.My pharmacy must pass the DIR (direct/indirect renumeration) fees to each customer who has Medicare part D. I need to find a chain pharmacy. I went to Walmart, Walgreens, CVS, Sams club and a few more. Everyone of them refused citing the CDC guidelines as law. I recorded 2 refusing to fill it. After 3 months I found a local chain pharmacy who would feel it for me. I've used the pharmacy for over a year.

From: Daffodil Hill
To: NCIPCBSC (CDC)
Subject: CDC Guideline Revision
Date: Wednesday, July 29, 2020 2:48:46 PM

Thank you for allowing patients to comment on the impact of the 2016 Guidelines and upcoming revision of those guidelines. Unfortunately. the impact cannot be expressed adequately in an email.
I have been a patient for many years at world renown HCC . I have MCTD (lupus and scleroderma) . I refused any medication until a necessary surgery failed and left me with damages which can never be reversed. I spent 2 yrs continuous in PT - 3x weekly. I then was under Chair of PM. He did every procedure available, NSAIDS, which worsened my esophagus damaged by scleroderma, yrs of conservative medications which I had severe reactions to most. They finally tried a medication after failure of all interventions incl. repeated blocks, injections , and other TX available. It took edge off, but I had no expectation of complete relief. The PM then said I needed to be managed on medication remainder of my life, and he referred me to the Chair of PM&R to assume responsibility for my care. We then commenced with every ALT including massage,acupuncture, reflexology , homeopathic, years of CBT and counseling as well as multiple devices my Dr. thought may help that were used by PT.,and several others incl.pool therapy, TENS, bracing, and PT sessions at least 2x yearly as allowed by insurance. 4 SCS were implanted .Each device kept failing, and my pain levels increased with severe shocking. After 6 yrs, I had explanted , and I have permanent nerve damage , scar tissue from multiple replacements, scar tissue from early surgeries which are well documented. This year my PM&R retired. Prior, he had spent hours compiling a summary of all failures and TX, medications, long list allergies. My new PM&R didn't even give me the courtesy of a face to face, or speak with me on telephone. He apparently felt no need to examine me himself, ignored findings and reports of additional pain DX as well. He had a PA inform me that he would not continue my medication. I have not noted the severity of my esophageal problems, and Botox injections are needed to keep me from choking frequently from multifactorial issues incl. scleroderma. When a person begins to choke , it is very frightening. I require a low dosage of xanax in addition to my opioid. With the current environment caused by the 2016 guidelines ,and now, the proposed dangers of LTOT, how do you expect patients who have failed every tool in your unsuccessful and limited tool kit for physicians to manage a patients pain? I have never increased my dosage,contrary to reports of continuing escalation of opioids. In fact ,an internist who had no knowledge of my complicated history as well as my failures of TX ,abruptly cut my dosage by 1/3 while my PM& R was out of town. It was a new physician, nd the EHR did not go back far enough to include my history. They were merging to a new EHR vendor, and many records had not merged successfully. She never examined ,or gave me opportunity to explain all TX options had been exhausted. I have not been able to even resume my dosage which had taken years of adjustments, and I had no AE to my medication. I was able to enjoy outings with my family , watch my grandchildren participate in sporting activities. dinners with friends, and was a Certified Professional genealogist which took 2 yrs of ntense education and had many well pleased clients that I had completed research projects on their family lineage. I have used my genealogy as a diversion tactic which worked well until the abrupt taper. Why do rare diseases not meet or are listed in your criteria for deserving PM? Please address and widen the scope of diseases, especially the rare diseases like mine. CRPS rates higher on the McGill pain index than amputation of a digit. Few physicians have education needed to manage it , and research funding is very low. Physicians need to be able to RX for individual patient needs. MME is unscientific, and each individual deserves care specifically tor their body and

metabolism. I deserve to be able to have my pain managed, so that I can participate in PT to get in condition and strengthen my muscles to avoid any unnecessary injuries. I want to be active and deserve the medication which worked when other failed. Given the years , cost, adverse reactions, and difficulty in accessing a successful treatment medication, why should I have to endure additional harm and uncontrolled pain in trying an unknown medication. I have spent 20 years at same HCC and I have been through enough trials to last a lifetime. My EHR clearly proves what I have written. I know how my body responds ,and I know consequences of AE. I don't want to be forced on a another medication which is also an opioid , and is worse to taper than my medication that has worked. I deserve to be allowed a reasonable amount of break through medication which which took the same long process of finding the one medication in which I didnt suffer an AE. Emergency Rooms are a last resort, and I had such a dangerous and almost life threatening event when I had a medical necessity for an ER, and the lack of testing and proper evaluation almost cost my life. I was out of town, and the physician would not look at my records on my app and was trying to force a medication to which I was highly allergic. My husband had to get the hospital administrator involved. ER was claiming they had severe shortage of medication. The administrator was a voice of reason ,and the situation was resolved. I was fortunate my husband is highly knowledgable regarding my condition ,and he is well aware of my allergies and potential of fatal harm. This needs to be addressed. I have been told by others who almost had the same life threatening encounter. Emergency Rooms are not taking time to fully assess the patient and innocent lives have been lost because of this. I'm very distressed by the CDC allowing special interest groups to direct the healthcare I deserve. I'm so frustrated by my activities being severely restricted by uncontrolled pain. Return the Dr./ Patient relationship. Government agencies should allow MD's autonomy to treat each patient on individualized basis, rather than your strict, unscientific, and the very low quality of the research. The number of patients and veterans who have committed suicide has risen dramatically. You have the records, and our Veterans deserve to be honored for their sacrifice and not have their injuries ignored. Recent research is a concern as well, as it has been biased against patients with pain and inaccurate conflation of illicit mfg drugs flooding our borders, and yet RX prescriptions have decreased to lowest levels in yrs, while overdoses have risen. In addition, physicians are leaving pain management and physiatrist as well creating a critical shortage of trained physicians. It is impossible to access a new physician when patients must relocate.Please change the current G/L ,and allow us the freedom allowed other patients who are not as unfortunate as those with painful disorders. Science still allows their conditions to be treated. You are tasked with the lives of millions of patients like me who have exhausted every mode of treatment. Your tool kit doesn't factor those of us who have tried every TX currently available. Please, I beg you, I deserve to function as I did when I had access to the medication that took edge off , and yet it did not give me complete relief. This is America ,and I thought we would never be faced where cancer patients cannot die comfortably. I watched my mother die wretched in pain, and my father suffered greatly. Now , unless you change the G/L, I will die just as my mother, and my children will forever carry that image for remainder of their lives. My final request is for you to monitor the outcomes of patients tapered abruptly from medications which gave us QOL. We should not be forced to live with levels of pain uncontrolled. This is akin to physical torture. Even though I had to relocate I've had to travel long distance to access my same HCC because physicians refused to accept me as a patient and prescribe the medications which are vital for me not to suffer greater amounts of uncontrollable pain. My future is very uncertain as I continue the search for a local physiatrist to treat me. I'm now phoning areas within 100 miles. My former PM& R has tried to colleagues , yet the DEA closed many clinics in our area, and Drs. are afraid to RX. Medical necessity is meaningless, and we cannot relocate again or my husband would loose his

income. He is working past the time he had planned to retire because the healthcare expenses not covered by insurance have created a financial burden for us.

From: Dave Mayberry
To: NCIPCBSC (CDC)
Subject: Pain symposium
Date: Wednesday, July 22, 2020 10:48:34 PM

I'm David Mayberry, a chronic pain patient, with failed lumbar lower back surgery x3, neuropathy, and spinal stenosis. My medications were not tapered, but cut off by doctors in Oregon, hiding behind your "guidelines"....I'm now on bupenorpheine, which does NOTHING for pain, so here I suffer. I relish the opportunity to be questioned and to relate my pain management experiences, where apparently Cymbalta is used extensively off label for pain. Unfortunately, my nephrologist says this is murder on my kidneys, and deemed me allergic to it. The p.m. doctor then prescribed 2 strengths of this drug to me, and signed his report...Right under where it said Cymbalta under drug allergies...This is the least egregious error in my pain management, and I'll be happy to tell you more. My phone number is (541) 206-5935.

Sent from my iPad

From:	David Acevedo
To:	NCIPCBSC (CDC)
Subject:	Meeting of the Board of Scientific Counselors, National Center for Injury Prevention and Control - Written Comment
Date:	Wednesday, July 22, 2020 7:42:25 PM

Board of Scientific Counselors, National Center for Injury Prevention and Control, et al,

Shocking. No mention of the horrific, widespread harms caused by the 2016 guidelines...

Overdosing is a violent, nightmarish way to die.
Overdosers are not among millions of abandoned severe pain patients seeking productivity and normalcy.
For the false narrative about medicinal opiate/opioid prescribing there is SUFFERING, untimely death and suicide and ethical Doctors of Medicine charged, prosecuted and convicted and imprisoned unjustly.
Let us disillusion the country again about the realities of untreated severe pain...

"Woe to those who are saying that good is bad and bad is good, those who are putting darkness for light and light for darkness, those who are putting bitter for sweet and sweet for bitter!" Isaiah 5:20,21

Regards,

David D. Acevedo
Waukesha, Wisconsin

From: Dawn Witek
To: NCIPCBSC (CDC)
Date: Tuesday, July 28, 2020 3:53:14 PM

I have chronic pain in my low back(19 yrs) and my neck(13 yrs). I have tried everything to relief the pain from non opioids and many different combinations of them, multiple sessions of physical therapy, pool therapy, traction control, tens unit, injection(multiple times), chiropractor, CBD oils(many different milligrams), hemp, ECT. All these either gave me no relief or it intensified the pain. It took years before I was given opioids. Everything effects and increases, intensifies my pain from sitting(I can't sit for to long, the harder the chair the faster it increases the pain), standing up from sitting position, standing in one spot, walking(any distance), even laying down(even if I lay down for to long). Im not an addict,I take them how their prescribed. Opioids were the only thing that gave me some relief, so I could function daily. My pain was managed before the 2016 guidelines came out. My opioid medication was reduced in half, now I'm in excruciating pain. I need the opioids to function, do daily activities. Ever since my pain has increased and intensified I've been struggling with suicidal thoughts, so many other pain patients have commuted suicide, the suicidal rate in pain patients have skyrocketed. I DON'T WANT TO DIE. It is inhuman to let people suffer like this when there is medicine out there to help them but their denied it. Doctors became afraid to prescribe opioids to their patients in fear of losing their licenses and or go to jail. I don't see how someone in government or law enforcement thinks that a patient is on to much and that the patients don't need to be on opioids at all or they don't need to take so much opioids. The doctor is the one with the education not government employees or law enforcement. The 2016 guidelines came out to help or stop the overdoses and or deaths from opioids. But its not the prescription opioids that is causing the overdoses and or deaths, its street drugs(herion and illicit fentanyl). After the guidelunes came out patients prescription opioids were either rapidly reduced or completely cut off. So with that happening the overdoses and or deaths should have slowed down rapidly or completely stopped, but that didn't happen. They were still skyrocketing, that proves that the cause of the overdoses and or deaths isn't prescription opioids it's street drugs, herion and illicit fentanyl. So why are the guidelines still in play? They need to be taken down or removed. Government and law enforcement needs to stop targeting doctors, because they never went for school on how to help patients and or know what a patient needs. We (pain patients) don't want to suffer no more, we just want to be able to function. Please help because I I don't want to suffer like this any more, so if I don't get my pain managed my choices are either- turn to street drugs to get relief or commit suicide, I know many other pain patients think the same or I know their suffering the same. When we are suffering our families are suffering also. Why isn't any body fighting for pain patients lives to be saved, to stop the suicide rate from skyrocketing in the pain community? Why doesn't our lives matter? Your standing up trying to save a criminals(their on street drugs) life from overdosing because the cause of the overdosing is street drugs, that was proven when the overdoses and deaths were still skyrocketing after every bodies opioid prescriptions were reduced and or cut off completely. But no body is willing to stand up for a pain patients life and they are law abiding citizens. We just want our lives back, we want some type of quality of life, we want to function again. In order for that to happen though we need our opioid medication back.

From: Delorse Croissette
To: NCIPCBSC (CDC)
Subject: Task force for opioids
Date: Friday, July 31, 2020 9:08:17 AM

I know that scientific data can be munipulated to whatever the reaearchers wants it to be. Double blind studies seem to have NO meaning ay CDC and its deemed cruel and inhumane punishment for people in pain to go with medications.
Here is what is happening in a nutshell. Its called Greed. The new opioid on the market has a big lobbiest organization to say the older opioids are bad. That is not even the truth. The illicit drug crisis is from Mexico and China being cut into heroin Meth and Cocaine and people are dying. There is not 72,000 opioid related deaths and this needs to be clarified. Also its been scientifically proven that the number of those with addiction hasnt reason since the 1920 the only thing that has risen is the number of Americans. Enough with the nonsense. We are tired of being apart of this horrific experiment that brings back the Tuskgee Airman experiment . We know this all stated with NIH and the ACA and then FDA turned this down and now HHS has come on Board.
As Sargeant of CIAAG and State Leader we should be allowed the ability to have a say in what happens in our health care. The Dr/Pt is now gone. No addict actually goes to a dr so urine test and pill counts are a nonstarter in the opinion of majority of pain patients. MME is a nonstarter, those of us like myself that has a rare 1/1000000 rare incurable disease 90mme does very little after an episode. Stiff person is painful and you all have no clue. Only patients can tell you how much or how little pain they are in. Thats is what should matter patient centered care with a choice in their tool.box of medications and alternatives treatments they can do. The DEA needs to stay out of drs office that are not doing anything wrong even if they do write medications according to a person disease

Take my husband who has progressive parkinson been turned by insurance to pay for his over $3400 medications 1mg twice daily of a benzodiazipine and afyer he jerks and ahakes for thirty minutes he has severe musvle cramps and was denied by an algorithm for the Drug Soma. This is wrong. Wromg in more ways then one.

Thank you
Delorse Croissette Sargeant CIAAG

From: Desiree Lyon
To: NCIPCBSC (CDC)
Subject: porphyria pain
Date: Tuesday, July 28, 2020 5:39:04 PM

If you are a patient, please identify if you mostly experience acute or chronic pain and if you feel opioid pain medications have mostly helped you, mostly harmed you, neither, or an even mix of both

My name is Desiree Lyon. I suffer from on of the Acute Hepatic Porphyrias (AHP) called Acute intermittent porphyria (AIP) , a a rare inborn error of metabolism that is one of the most painful in human kind. Unfortunately, I had over 100 attacks and was left with severe nerve damage/neurapathies.

The acute porphyrias also are pharmacogenetic disesaes , which means there are a host of drugs porphyria patients cannot take without causing critical attacks. Among these drugs are pain medications. In fact, the only pain medications that patient can take with AHPs are opioids. Although this sounds false, this has been veryifeid with the most renown experts. It is already a commonly demeaning experience to ask for pain medication but to be classed in the opioid set is distressing . I founded the American Porphyria Foundation, was executive director for 30 years and am now global director of what is now a 13,000 member organization. Yet, when doctors find out I use opioids for severe nerve pain, they change their attitude toward me and see me as a drug seeker. They ignore the fact that pain medications enable me to work and live a normal life.

Sadly, this is not uncommon for people in constant pain. Thus, patient endure both emotion al and physical pain. My pain doctor is a neurologist at a famous cancer center. She has been with me during a bad attack and knows well my circumstances. I would like the chance to explain pain from a patient perspective and the challenges in mitigating the pain. They are far too many for a suffering person. Thank you,

Desiree Lyon
Global Director
American Porphyria Foundation
www.porphyriafoundation.org
713-857-0995 Mobile
301-347-7166 Office

From:	Djb
To:	NCIPCBSC (CDC)
Subject:	Please advise states to retract laws
Date:	Wednesday, July 22, 2020 10:56:31 AM

Please urge states to revoke laws made on 2016 DRAFT opioid guidance and tell the DEA stand down. I've attached the letter from the AMA which I'm sure you've see. Let's go with the FDA recommendation on the label effective immediately for those already on opioid therapy.

https://www.ama-assn.org/press-center/press-releases/ama-urges-cdc-revise-opioid-prescribing-guideline

Sent from my iPhone

From:	Doryn Chervin
To:	NCIPCBSC (CDC)
Subject:	NCIPC feedback about priorities and focus
Date:	Tuesday, July 28, 2020 5:31:28 PM

Thank you very much for the opportunity to provide feedback to NCIPC about important priorities that you may want to consider in the service of improving the health of Americans. One of the major issues that require a greater national focus on is the impact of benzodiazepine injury and benzodiazepine withdrawal syndrome. The interventions to make a difference in this type of injury are within NCIPC's purview, partnerships and strategies.

Many Americans and others across the globe suffer severe morbidity due to the tolerance to inappropriately administered benzodiazepines (over 14 days), the often devastating impact of benzodiazepine withdrawal syndrome (often due to poor deprescribing practices), and long-term injury of benzodiazepines withdrawal. In addition, it is my belief that a focus on benzodiazepine injury will assist NCIPC in helping to reduce the opioid crisis. To be optimally effective requires a focus on benzodiazepines. Benzodiazepines co-occur in many opioid-related deaths, and it is imperative to see if a meaningful reduction in inappropriate benzodiazepine use would help save many people who are currently at risk of opioid and benzodiazepine co-occurrence.

As a board member of the Alliance for Benzodiazepine Best Practices (www.benzoreform.org), and a long-standing public health professional, I respectfully submit these comments.

Doryn Davis Chervin, Dr.P.H.

From:	Douglas Wisor
To:	NCIPCBSC (CDC)
Subject:	NCIPCBSC@cdc.gov
Date:	Monday, July 27, 2020 9:12:45 AM

To Whom It May Concern:

My name is Dr. Douglas Wisor, MD and I am a board-certified interventional pain management (IPM) physician and CEO of the National Spine & Pain Centers (NSPC) MSO which operates the nation's largest network of pain management centers across 11 states with 80+ sub-specialty board-certified IPM physicians and approximately 150 NP/PA extenders. Our affiliated providers & centers provide comprehensive acute, sub-acute and chronic pain services for patients with a diverse array of painful medical conditions. IPM treatments made available to patients of our affiliated practices are designed to improve pain control & maximize functionality, while avoiding whenever possible opiate utilization/dependence and reduce what are often ineffectual and unnecessary surgical services that can further lead to chronic pain and debility.

I would welcome the opportunity to be interviewed or be included o/r provide a Congressional panel of NSPC-affiliated physician experts in pain management to be interviewed by any relevant Congressional Committees (such as Appropriations) on any host of relevant issues including the value of IPM services to avoid or minimize opiate and surgical utilization, modification or expansion of CDC guidelines, review of the HHS Best Practice Task Force, and how making IPM services available to all patients via their PCP can help avoid further spikes in opiate overdose deaths, which have only continued to escalate during the current COVID crisis.

Please reach out if you would like to pursue this matter further.

Regards,
Doug

Douglas Wisor MD
CEO
National Spine & Pain Centers
C: (703) 927-5772
dwisor@treatingpain.com

From: Larson-Steckler, Elizabeth A.
To: NCIPCBSC (CDC)
Subject: Comments
Date: Thursday, July 23, 2020 10:33:33 AM
Importance: High

Good Morning,

I would like to add my comments as I was not able to speak yesterday. First, I truly do appreciate the committees inclusion of patients and caregivers. I am the wife and mother of family members that have/had hereditary pancreatitis. My husband's hereditary pancreatitis led to pancreas cancer. He died due to complications of treatment. My two children diagnosed at age 1 and 2 have both struggled with this disease. They both underwent auto islet transplant total pancreatomy and splenectomy. Both had multiple complications and were left with many issues; chronic pain, malabsorption, GI issues, diabetes, dysautonomia, heart issues, malnutrition among various other issues. Currently, they are 18 and 21.

As a parent, I have attempted to find appropriate care for my kids to address their pain. I do not like the fact that they are on opioid pain meds for many reasons. The current climate has caused a great deal of harm for both my kids. They have been labeled 'addicted' by physicians who do not look at entire picture. For example I have been concerned about their malabsorption of medications and no one has taken a close look at this. I know their meds work some times and other do not. Example, my daughter was in hospital and urine test was given. It came up negative for opioids. Based on this they labeled her 'addicted', removed meds from her (no titration) and had a social worker called into talk to her about treatment. I was out of town at time, only parent. Fortunately her therapist intervened and filed a report. She was given opioids and took another test. Came back negative. The trauma they have faced by not being believed by physicians has taken a toll. Once they were labeled it has been so difficult to receive necessary care.

I believe in an interdisciplinary approach as well as implementing a multimodal approach. This has been difficult to ascertain. I have had to reach into my pocket and pay for other treatments not covered by insurance. I also enrolled my kids into a renowned pain program. I find the program we went to very traumatic. There was no options to stay on pain medication, just application of other modalities. They also wanted to take my kids off a whole host of other medications for their GI issues. They ignored my daughters concerns. Told me it was common for kids to increase their complaints while in program. I ignored her, following the rules. She ended up in hospital with thrush. I agree with the implementation of various tools and treatments. I was excited to be able to access these tools for my kids but how it was done was shaming and blaming. I do believe that my kids could have stepped down a bit on opioids with other tools and treatments but it was not allowed. Care should be individualized.

I am not only a parent but I am also one of the founders of the Foundation of Childhood Pancreatitis as well as founder of Navigations, which assists parents and caregivers with navigating care of children with chronic and complex health issues. I receive numerous calls from parents and caregivers many in regards to treatment of pain. The stories are horrific in such violation of 'do no harm'. One child was in flare. Parents had brought her into ER. She was admitted. Medical team

used lavender oil to assist with pain. I don't have any issue with using supportive techniques but that is the only thing that was provided. Another youth was left screaming in pain after an ERCP. Both physician and nurse indicated that she should not have pain and provided nothing. The nurse indicated to the mother that the child was struggling with addiction issues. I assisted this mother to get her child airlifted to another facility. It was found that the physician, when doing ERCP had gone into the pancreas NOT bile duct. This young woman received care and has since turned 18. She does not trust medical system or physicians. Her illness dictates that she does need care but due to experience and the trauma involved she does not go in regularly but ends up in crisis. Many youth are ending up being treated by psychologists. One ended up in pysch hospital. Fortunately she had attack while there and was rushed to ER where the physician finally diagnosed as hereditary pancreatitis. How traumatizing not only for youth but for parents.

In order for these youth to engage in care, they need to be respected and not traumatized. The system is creating 'noncompliant', 'difficult' patients but they do not see their role. For me the issue is just not access to opioids but better, research, earlier care, more competent care, individualized care as well as the ability to access various treatments and tools. I have witnessed both my kids at multiple times wishing they were dead because of health issues, pain and the bias in stigma currently inundating the medical field regarding opioids.

Kids with pain should be immediately referred to a pain specialist. Research has demonstrated that it is critical, if not addressed will lead to chronic pain and as I have witnessed trauma. Sadly, there is not a lot of places that truly know how to address pain. There are pockets but for many unable to reach due to many barriers. They only thing that has given them a bit of quality of life is opioids. Last year, the pain physician that my son trusted. That treated his dad, was told by his organization to cut off all individuals on pain medications. They had received a letter from our state CMS to titrate all individuals to 90MME (which my understanding was not if it was a pain physician) this was pushed federally by CMS. No referrals were provided to those being titrated. I was fortunate knowing my son's rights and was the only one to get a referral. However great damage was done. My son trusted his pain doctor. He sat and cried for days about having trusted this doctor and the doctor no longer cared about him. Most people on LTOT, have tried many things. As I said, I want other options. My kids should have received pain care early on in a compassionate way. The current climate you are suspect if you utilize pain meds. My kids are 18 and 21 and have really been harmed by physicians who have ignored their pain or indicated it was psychological. I do believe that their pain can be impacted by mood as well as mood impact pain – definitely believe this but to have physicians ignore and dismiss and rely only on psychological tools is not helpful for those with chronic pain.

Truly wish there was other options. My kids should have had pain addressed earlier in their journey. I actually advocated for that as well as a pain psychologist but their transplant team only had one visit done with them. That is not effective. Shame and blame should not be utilized or allowed at many of these pain facilities. All individuals should have access to multimodalities of care inclusive of pain medications. Through our journey pain physicians and other doctors pushed other types of care on my kids. Both underwent blocks – which they should not have due to their islet transplant. They came out worse. My daughter who only had stomach pain, now has back pain. Islets were destroyed all in attempts to remove them from opioids.

Thank you
Elizabeth Larson-Steckler

The FED UP! Coalition

FED UP! A COALITION TO END THE OPIOID EPIDEMIC

A call for immediate, coordinated and comprehensive federal action to end the epidemic of opioid addiction and overdose deaths

June 15, 2020

Robert Redfield, M.D.
Director
Centers for Disease Control and Prevention
Department of Health and Human Services
1600 Clifton Road
Atlanta, GA 30329

Submitted via regulations.gov

Re: Management of Acute and Chronic Pain: Request for Comment
Docket No. CDC-2020-0029

Dear Dr. Redfield,

More than 500,000 Americans have now died in the opioid epidemic. Approximately 2 million suffer from opioid use disorder. These are the consequences of the change in prescribing practices for chronic pain that occurred in the late 1990s and early 2000s. The resulting overprescribing of opioids occurred largely due to multiple incorrect beliefs:

1. Opioids are of significant benefit for those with chronic pain.
2. Risks of opioid addiction are much lower than had been previously thought.
3. Addiction risk is lessened by extended-release opioids.
4. Opioids present no real risk of addiction when a patient is in pain.
5. The mantra from the pharmaceutical industry and its physicians that there are two groups of patients taking opioids, chronic pain patients and drug abusers.

The FED UP! Coalition is a national coalition of local organizations with a common goal of bringing the opioid epidemic to an end. Most of those who organized the coalition lost children in the opioid epidemic. Many of our children began their journey to addiction and overdose death with medication prescribed to them for acute or chronic pain by well-meaning physicians. Hence, this letter will focus on the role of opioids in acute and chronic pain.

In the past several years, we have seen a decrease in the overprescribing of opioids in the United States. Yet rates of opioid prescription remain far higher than they were before the mid-1990s. And opioid deaths have continued to escalate as a late-occurring consequence of overprescribing of opioids.

The FED UP! Coalition

FED UP! A COALITION TO END THE OPIOID EPIDEMIC

A call for immediate, coordinated and comprehensive federal action to end the epidemic of opioid addiction and overdose deaths

Over the past few years, there has been increasing recognition of the surprising frequency with which opioids given for short-term acute pain become long-term opioid treatment. This has led multiple surgical specialties to come up with protocols to minimize addictive risks in management of post-surgical pain. These protocols make it clear that opioids, if needed for acute pain, should be prescribed at the lowest effective dose, for the shortest time possible, and in the smallest possible quantity. Other specialties have joined in the effort to minimize unnecessary opioid use. Anesthesiology has become increasingly sophisticated in the development of nerve blocks to deal with acute pain.

There really should be no controversy at this point about the approach to chronic pain. The evidence that there is a subgroup of chronic pain patients who show long-term clinical benefit from opioids and low risk of addiction remains non-existent.

The current controversy has to do with a group of chronic pain patients who believe that the opioids have resulted in pain relief far in excess of what they obtain from any other treatment. This vocal group, supported by its backers within the pharmaceutical industry, continues to exercise influence far beyond both its numbers and beyond the lack of scientific evidence for their position.

While their bugaboo is the 2016 CDC Guideline, since the issuance of the Guideline, there is considerable further evidence that opioids are not appropriate for treatment of long-term pain.

The Krebs *et al*. 2018 study at the Minnesota VAH of 240 patients with moderate to severe chronic back pain, hip or knee osteoarthritis demonstrated the lack of superiority of treatment with opioids to non-opioid treatments in patients with chronic low back pain.

The 2018 Busse *et al*. meta-analysis of 96 trials consisting of more than 26,000 patients treated with long-term opioids for chronic pain showed no evidence that treatment of chronic pain with opioids is any more effective than tricyclic antidepressants, NSAIDS, or anticonvulsants.

The 2019 Klimas *et al*. study showed that risk-stratification tools were of no benefit in locating a group of patients to whom opioids could be prescribed with reasonable safety.

All these have indicated, as is made clear the 2019 Wood *et al*. commentary piece, that patients with chronic pain who are not on opioids should not be placed on opioids: the risks simply outweigh the benefits.

The only real controversy at this point should be about how to get funding for multidisciplinary, multimodal pain clinics. Even as recently as the 2019, the HHS Interagency Best Practices Task Force for Pain Management stated that for treatment of chronic pain we need multidisciplinary, multimodal treatment with expanded use of non-opioid pharmacological treatment, restorative interventional behavioral and complementary approaches.

A call for immediate, coordinated and comprehensive federal action to end the epidemic of opioid addiction and overdose deaths

This is where the CDC's emphasis must be at the present time.

Yours truly,

Emily Walden

Emily Walden
Chair, FED UP! Coalition to End the Opioid Epidemic

Daniel A. Busch, M.D.
Chair, FED UP! Advocacy Committee

References:

Busse JW, Wang L, Kamaleldin M, et al. Opioids for Chronic Noncancer Pain: A Systematic Review and Meta-analysis. JAMA. 2018;320(23):2448–2460. doi:10.1001/jama.2018.18472

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Krebs EE, Gravely A, Nugent S, et al. Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial. JAMA. 2018;319(9):872–882. doi:10.1001/jama.2018.0899

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July 28, 2020

Board of Scientific Counselors
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway, MS F63
Atlanta, GA 30341

Subject: Comments re Board of Scientific Counselors meeting, July 22, 2020

Thank you for the opportunity to submit written comments. I write on behalf of Families for Intractable Pain Relief (FIPR). I have several major points I wish to bring to your attention.

1. Although not acknowledged by some parties, **there exists a subgroup of chronic pain patients who develop constant severe pain accompanied by such severe impairment of physiologic and psychosocial functions that the person is incapacitated and may suffer an early death**. Research in recent years has now determined that these unfortunate individuals have transformed from a simple chronic pain state into a physiological and pathologic state that should properly be called "Intractable Pain Syndrome" (IPS). This syndrome is not a symptom or disease, but a complication of an underlying, painful disease or injury that produces excess electrical impulses that travel into the brain and spinal cord (central nervous system or CNS) and create pockets of tissue-destructive inflammation. Loss of CNS tissue in this process may include the neurotransmitter-receptor systems that control pain and regulate the cardiovascular, endocrine, and immunologic systems. With this loss of tissue, the afflicted persons develop constant pain and measurable evidence of cardiovascular, endocrine, and immunologic abnormalities. Hence, the systemic signs and symptoms indicate a specific syndrome of multiple body-wide manifestations termed Intractable Pain Syndrome (IPS). **The Tennant Foundation has recently initiated the Intractable Pain Syndrome Research and Education Project. The goal of this project is to bring recognition and treatment of the syndrome to pain care and to foster its prevention, since it is a devastating, catastrophic medical condition.** This unfortunate subgroup of chronic pain patients has essentially been overlooked and forgotten in current treatment guidelines. Information about IPS can be found at www.intractablepainsyndrome.com.

2. The 2016 CDC Guideline for Prescribing Opioids for Chronic Pain is regarded by many as deeply flawed for various reasons that we will not address in this submission. However, **we believe that persons who suffer from Intractable Pain Syndrome are being denied effective pain treatment as a result of the MME thresholds stated in the Guideline.** The use of opioids to treat intractable pain has been the mainstay of treatment since about 1960. Indeed, until now opioids have been the only thing that has helped many persons with intractable pain. Many such persons have been helped by opioids without significant side-effects, abuse, or overdose issues. These patients are often persons who have been ill with IPS for many years, whose IPS evolved to the catastrophic level of severity before finding treatment, and who have been stable on their opioid dosage. It is our position that current patients with IPS should be left on any successful opioid dosage and not be forced to taper or discontinue. We believe the use of potent opioids to treat IPS in the future will be progressively reduced over time, because there are now tools available that enable physicians to diagnose and treat persons with IPS at an early stage, and prevent the development of IPS in patients whose chronic pain has not yet started to cause central nervous system inflammation. **We recommend that CDC 1) withdraw the CDC Guideline, 2) lead the medical community in supporting physician discretion to diagnose and treat pain using IPS treatment protocols, 3) stop discouraging appropriate use of opioid medications as a last resort**

treatment for persons suffering from IPS, and 4) support the implementation of a REMS program to provide for the effective treatment of these patients. Opioid pain medications can be used safely, even at high dosages, when prescribed by knowledgeable physicians, including experienced family practitioners and internists. Failure to change course will result in continued suffering of many severe pain patients and bring about the early death of many more…either by their own hand or from the catastrophic effects of undertreated or untreated pain.

3. In 2019, FIPR submitted comments to the HHS Interagency Pain Management Best Practices Task Force. We submitted these comments to FDA in 2019 and to CDC in response to CDC-2020-0029. **We submit here for your consideration proposed "Policies and Best Practices" for treatment of intractable pain patients, in lieu of the current CDC Guideline or any revision thereof. FIPR recommends policies to address the overlooked condition of constant severe intractable pain, or Intractable Pain Syndrome, and to propose as best practices some approaches that have generally worked well for these patients.**

Individuals who have such pain do not experience remissions and frequent relapses. The pain level is extremely severe and it is constant with no remissions. Many of these patients have been treated successfully for long periods of time with opioid pain medications at high doses; those same patients have experienced great harm since the CDC Guideline for Prescribing Opioids for Chronic Pain was published in 2016 due to reduction or cessation of their opioid medications. FIPR's recommended language submitted here is consistent with the FDA's 2019 warning against forced sudden discontinuation or rapid tapering of opioids.

FIPR's Proposed Definition and Best Practices for Treatment of Individuals with Constant Severe Intractable Pain:

Definition of Constant Severe Intractable Pain

Constant severe intractable pain is defined as an excruciating, constant pain state without remissions that is not curable by any known means, causes adverse biologic effects on the body's cardiovascular, hormone, and neurological systems, and leads to a bed- or house-bound state and early death if not adequately treated. **This category of pain differs from chronic relapsing pain (addressed in 2.7.5 of the HHS Task Force report) in that there are no remissions at all; the pain is both very severe and constant.** Constant severe intractable pain can be caused by rare illnesses including adhesive arachnoiditis, some autoimmune diseases, Reflex Sympathetic Dystrophy (RSD) (also called Complex Regional Pain Syndrome (CRPS)), and genetic connective tissue disorders such as Ehlers-Danlos Syndrome and Marfan Syndrome.

Proposed Best Practices

The existence of such pain as defined above is not widely accepted, which contributes significantly to its under-treatment. Lack of awareness often makes these patients the victims of stigma and disbelief on the part of physicians. **These patients require comprehensive, compassionate palliative care which will likely require opioid pain medications, often at high doses, in addition to adjuvant treatments and therapies. The goal of treatment is to provide life-long pain relief sufficient to normalize physiologic and mental function and enable the patient to independently carry out activities of daily living to the maximum extent possible.** Patients with constant severe intractable pain are often met with great hostility and resistance because they are, by definition, incurably disabled and will have to take opioids for a long period, probably for the rest of their lives. In the absence of clarifying guidance about what to do with these seriously ill patients who have already tried and failed standard treatments, pain

practitioners accepting such patients for care will be likely to tell them they must lower their opioid doses and essentially "start over", requiring them to jump through hoops already tried and failed.

Recommendations:

- 1a: Educate physicians, pharmacists, law enforcement, and regulatory agencies at all levels to the fact that pain of this nature exists, is totally debilitating, and leads to early death if not adequately treated. Endorse the long-term use of immediate or extended release opioid medications at whatever dose is required to manage the pain, when all efforts at standard care have failed. Practitioners should continue successful treatment protocols for long-term stable "legacy" patients who have demonstrated that benefits exceed risks. Practitioners should avoid mandating changes to treatment regimens that are succeeding, as changes in medication protocols, once a patient is stable, are frequently destabilizing and very harmful to these complex, often frail patients.
- 1b: Emphasize the following in educational efforts to combat stigma against these patients:
    - Patients who request a specific opioid medication almost certainly know what works best to manage their pain. Such requests should not be construed as "drug-seeking" behavior. Also, physicians should believe patients who report that a medication isn't working or intolerable side effects are being experienced.
    - **Successful pain care of these patients is best measured by 3 outcome metrics: 1) pain control, 2) functional capability, and 3) quality of life as reported by the patient with confirmation by a family member**. A **focus on MME is inappropriate** as many of these high-dose **"outlier"** patients are limited in their ability to metabolize medications due to genetic variance, gastrointestinal malabsorption from diseases and surgeries, or dysfunctional receptors.
    - For successful patients, months or years of effort have likely gone into developing the personalized treatment protocol that works. In these cases, **the best practice is to keep doing what works.** For these patients, the current protocol represents the **pinnacle of individualized, patient-centered care**. Forced tapering or forced change in regimen brings about unnecessary suffering, disruption of life, and loss of quality time for patients who have already suffered greatly before finding their successful regimens. Such forced change not only disrupts the lives of these patients during the transition, but may never result in outcomes as good as those produced by the regimen from which the patient is being forced to change.

As a group specifically committed to advocating in support of severe intractable pain patients whose life-altering pain is caused by very serious incurable disease conditions, FIPR categorically rejects the notion that high doses of opioids are never useful or helpful to any patients. There is a very wide range of therapeutic opioid doses among our patient members. Many are able to manage their pain effectively on doses in the 100-200 MME range, while others have fared well on dosages in the 2000-3000 MME range.

4. In the last few years, many physicians who treated chronic pain have stopped taking pain patients, many pain specialists have left medical practice altogether, and many exceptional pain specialists who treated the most severely ill have been targeted, raided, and/or charged with wrongdoing. It is clear that, in the current atmosphere surrounding opioids, pain doctors will not come back into practice unless and until the Federal government provides protection in the form of criteria to identify which patients should be considered for high-dose opioid therapy. High-dose opioid therapy is not new. It has been practiced as a last resort treatment by intractable pain specialists for decades. High-dose opioid

therapy can be a legitimate medical practice for pain patients for whom all else has failed, provided appropriate diagnostic criteria are applied.

As mentioned in section 1 of this comment, The Intractable Pain Syndrome Research and Education Project has recently been initiated to raise awareness of this devastating syndrome and to promote further research and education. **A comprehensive report, The Intractable Pain Syndrome: A Call for Recognition and Prevention, presents the background, history, and basics of the Intractable Pain Syndrome (IPS) as well as the rationale and means to treat it.** It serves as a resource for patients and caregivers, as well as medical professionals. The report provides objective criteria for the diagnosis of IPS and treatment protocols to help stop its progression. **FIPR endorses this report, the diagnostic criteria it establishes, and the treatment protocols described therein. The proposed diagnostic criteria and treatment protocols could serve as a starting point for implementation of a REMS program to provide for the effective treatment of these patients.** Absent such action by the Federal government, we face an ever-growing pain care crisis with too few doctors, too few dispensing pharmacies, and too many Americans needlessly suffering torturous pain and premature death.

The report, extensive reference lists, and case-specific information are available at www.intractablepainsyndrome.com.

Thank you for the opportunity to provide comments. Should opportunities for discussion become available, I request to be contacted and scheduled for such discussion. My contact information is provided below.

Sincerely,

/Kristen D. Ogden/

Kristen D. Ogden
Co-Founder, Families for Intractable Pain Relief

kristenogden@prodigy.net
cell: 804 731-2072

CDC JULY 22, 2020 COMMENTS

Presented by Fred Brown
Fredbrown3900@gmail.com

I have been a long-term chronic pain patient for over two decades, and the use of opioid medications for 22-years has been imperative, and only prescribed by my pain management physician. My name is Fred Brown, a patient, and an Advocate for Pain Patient Rights. I have brief comments that I would like to share with you; why you need to change the **Opioid Guidelines from 2016.**

I believe such added stress has been brought about due to the **Guidelines.** Many of the patients that have been injured are no longer with us, as they could not obtain their legally prescribed medications, and because of this, they began to find street drugs to relieve their pain; **or worse yet, used suicide to stop their suffering.**

We, as chronic pain patients, did not ask to be in this position, and each one of us has a **different story to tell**. I have gone through four cervical surgeries, which have **not** been able to correct the problems and have brought far more severe pain to me.

When the Guidelines in 2016 were being developed, why was it done without having at least one Pain Management physician as part of your Group? Further, my understanding is that much of this was handled in an incredibly quiet and with respect in a deceitful manner.

If pain can be relieved, why isn't it? **Why must patients** have to put up with such negativity when all that we want is to find a better quality of life. I agree that drugs such as opioids might not be needed for every pain patient. However, many of us find reduction of symptoms with the use of opioids, and in many cases, at a much higher dose than the 90MME level.

I believe that one who lives in chronic pain should also use other modalities with the pain medications, which can help them within their limitations.

I would appreciate your considering my comments from today. Thank you.

headsUPmigraine

COMMENT: Centers for Disease Control and Prevention
Board of Scientific Counselors,
National Center for Injury Prevention and Control
July 22, 2020

CONFLATION OF MEDICAL AND NON-MEDICAL OPIOIDS MUST END

NITA GHEI, PHD, JD

Good afternoon. I am Dr. Nita Ghei, Director of Research, headsUpmigraine, a volunteer patient organization dedicated to improving access to care for patients.

I would like to make just one point today: the conflation of medical and non-medical users, and legitimate prescriptions with illicit opioids has resulted in policies that have been disastrous to patients with chronic, progressive diseases.[1]

There is little doubt that the CDC 2016 Guidelines have been grossly misinterpreted and misapplied. This was an entirely foreseeable result. Once the CDC put numbers for opioid prescription levels that were considered "safe," it was almost inevitable that legislators and law enforcement would seize on them as a metric in the prosecution of the War on Drugs. Except this time the target was pain patients and our physicians.

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[1] See Anne Case and Angus Deaton, Deaths of Despair and the Future of Capital, Princeton University Press (2020), for an example of conflation. This view is regrettably prevalent in the economics and policy literature. The medical literature, on the other hand, consistently shows that medical and non- medical users are separate populations. See, e.g., Singer, J. A., Sullum, J. Z., & Schatman, M. E. (2019). Today's nonmedical opioid users are not yesterday's patients; implications of data indicating stable rates of nonmedical use and pain reliever use disorder. Journal of pain research, 12, 617–620. https://doi.org/10.2147/JPR.S199750; Friedman BW, Ochoa LA, Naeem F, et al. Opioid Use During the Six Months After an Emergency Department Visit for Acute Pain: A Prospective Cohort Study. Ann Emerg Med. 2020;75(5):578-586. doi:10.1016/j.annemergmed.2019.08.446 (less than one percent of patients had an opioid prescription, and they reported chronic pain); Alexander Y. Walley, MD, MSc; Dana Bernson, MP ; Marc R. Larochelle, MD, MPH ; Traci C. Green, PhD, MSc3; Leonard Young, MS, MA ; and Thomas Land, PhD, The Contribution of Prescribed and Illicit Opioids to Fatal Overdoses in Massachusetts, 2013-2015, PUBLIC HEALTH REPORTS 2019, Vol. 134(6) 667-674 (less than one percent of opioid overdose deaths in Massachusetts had own opioid prescription, according to PDMP).

The result was rapid, non-consensual tapers of opioid therapy of previously stable patients living with intractable pain. The most recent research shows that this increased the risk of death substantially.[2] However, for years, the sole metric used to assess policy success was decline in prescriptions, not patient outcomes. The tunnel vision that focused on cuts in prescription opioids has created a new problem – increased disability and lack of access of care for seriously ill Americans – without addressing the problem it was supposed to address. Now, almost 80 percent of surveyed primary care physicians are unwilling to take on chronic pain patients, even for basic care.[3]

The focus on restricting prescriptions is a solution for a non-existent problem – pain patients use their medications appropriately, according to multiple large studies, without SUD. The real opioid crisis today is lack of access to treatment by the 20 million Americans living with high impact, chronic pain. We are the biggest stakeholder in this policy debate, but we have no representation. Thank you.

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[2] Elizabeth M Oliva et al, Associations between stopping prescriptions for opioids, length of opioid treatment, and overdose or suicide deaths in US veterans: observational evaluation BMJ 2020;368:m283 https://doi.org/10.1136/bmj.m283 (Published 04 March 2020)

[3] Lagisetty PA, Healy N, Garpestad C, Jannausch M, Tipirneni R, Bohnert ASB. Access to Primary Care Clinics for Patients With Chronic Pain Receiving Opioids. *JAMA Netw Open.* 2019;2(7):e196928. doi:10.1001/jamanetworkopen.2019.6928

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July 28, 2020

Via Electronic Mail Only
Gwendolyn H. Cattledge, Ph.D., M.S.E.H.
Deputy Associate Director for Science
NCIPC
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mail Stop S106-9
Atlanta, GA 30341

Re: Comments on the July 22, 2020 Meeting of the Board of Scientific Counselors NCIPC Opioid Workgroup

Dear Dr. Cattledge:

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Delivered via email to NCIPCBSC@cdc.gov

July 29, 2020

Arlene Greenspan, DrPH, MPH, PT
Associate Director for Science
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway, MS F63
Atlanta, GA 30341

RE: CDC Guideline for Prescribing Opioids for Chronic Pain

Dear Dr. Greenspan,

Thank you for the opportunity to submit comments on CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. At Heron Therapeutics, our mission is to improve the lives of patients by developing novel, best-in-class treatments that address some of the most important unmet patient needs. We aim to develop patient-focused solutions by applying our innovative science and technologies to therapeutic agents with well-known pharmacology.[1]

Even in primary care settings, physicians should counsel their patients on avoiding opioid use for acute pain management before, during and after surgery. Specifically, the surgical setting contributes in three ways:

1. Exposure of millions of opioid naïve patients every year to opioids
2. Leaving close to a billion unused opioids in society ripe for diversion
3. Poor pain management and opioids are associated with the development of chronic post-surgical pain

Having acute pain and post-operative guidelines can reduce exposure to opioids, reduce opioid prescriptions and may lower the incidence of chronic post-surgical pain. For post-operative pain management, non-opioid multi-model pain management regimens after surgery should make opioids the last line of treatment options, not the first line. A greater focus on innovative non-opioids will reduce the need for opioids as well as opioid prescriptions.

Specifically, we are requesting the following:

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[1] Heron Therapeutics. About Heron. Accessible online: https://www.herontx.com/aboutus-main.

We urge the CDC to make patients expected to undergo surgery aware of the availability of non-opioid drugs for use during surgery, which have demonstrated the ability to reduce or eliminate opioid use.

Patient-centric care and prevention of opioid use in the perioperative setting is often a neglected component of addressing the opioid crisis. Opioid prescribing among U.S. surgical patients can be in excess of what is necessary for pain control, with many patients often receiving opioids unnecessary for adequate pain relief.[2] Moreover, patients who receive opioids post-surgery are likely to continue to use them after leaving the hospital.[3] For opioid-naïve persons prescribed at least one day of opioids, "the probability of continued opioid use at one year was 6.0% and at three years was 2.9%."[4] This finding by the CDC is echoed by another study, which found the incidence of new persistent opioid use after surgical procedures to be 5.9% to 6.5% and did not differ significantly between major and minor surgical procedures.[5] Additionally, studies suggest that 70 percent of all opioid tablets obtained by surgical patients go unused.[6] Because almost all (90 percent) of these drugs remain in the home in unsecured locations and leftover opioids are a risk factor for abuse, they are a safety risk and may lead to unintended consequences for individuals and society in general.[7]

With over 50 million surgeries in the U.S. annually and over 80% of patients discharged with an opioid prescription, this translates into as many as 2.6 million new persistent opioid users, of which as many as 600,000 may develop opioid use disorder as a result of surgery each year.[8] This is important to Medicare for two reasons: (1) opioid-related adverse events cost billions of dollars annually, and (2)

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[2] Bicket MC.et al. Association of new opioid continuation with surgical specialty and type in the United States. 2019. The American Journal of Surgery, DOI: 10.1016/j.amjsurg.2019.04.010

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[4] CDC. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015.* https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm

[5] Brummett CM, Waljee JF, et al. *New Persistent Opioid Use After Minor and Major Surgical Procedures in US Adults.* https://jamanetwork.com/journals/jamasurgery/article-abstract/2618383

[6] Hill, M.V., McMahon, M.L., Stucke, R.S., and Barth, R.J. 2017. "Wide Variation and Excessive Dosages of Opioid Prescriptions for Common General Surgical Procedures." *Annals of Surgery* 265(4): 709-714.

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opioid use disorder has nearly doubled among older Americans over the past 10 years.[9]

Opioid drugs are widely prescribed across the United States; however, chronic opioid use can lead to increased healthcare utilization and costs.[1-310] Previous work estimates that patients with chronic opioid use have 4 times higher mean total health care costs versus non-opioid users in the year after their opioid initiation, and have significantly more ambulatory visits, emergency visits and hospitalizations than their non-user counterparts.[11]

Chronic persistent surgical pain is an unrecognized adverse consequence of surgery. For example, as many as 30% of breast surgery (lumpectomy and mastectomy) patients experienced chronic pain, and for as much as a third of those patients, it was severe.[12] Opioid naïve patients who are prescribed opioids to manage that pain one week after discharge are 44% more likely to continue taking opioids at 1 year[13]

We can help break this tragic process by increasing patient and physician awareness of the availability of innovative non-opioid therapies, thus reducing opioid exposure for millions of patients annually and reducing the number of opioids in our communities. Making non-opioid multi-modal regimens the foundation of post-operative pain management and using opioids if necessary, can be an important step forward in preventing opioid use disorders that begin as post-operative pain management strategies.

Conclusion

Heron thanks the CDC for the opportunity to provide input on its update to CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. We encourage CDC Develop acute and postoperative guidelines for pain management and the use of opioids make prescribers and patients aware of the alternatives

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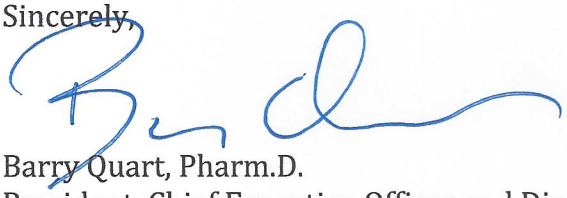
available to avoid opioid exposure during surgery, and thereby reduce the need for post-surgical opioid use.

We look forward to working with the CDC to ensure that all patients have access to vital therapies and products that can improve quality of life. Please do not hesitate to contact Mike Matthews at (858) 251-4453 or mmathews@herontx.com if you have any questions.

Sincerely,



Barry Quart, Pharm.D.
President, Chief Executive Officer and Director
Heron Therapeutics

From: smf53@aol.com
To: NCIPCBSC (CDC)
Subject: PUBLIC COMMENT - Guidelines for Prescribing Opioids for the Management of Chronic Pain
Date: Wednesday, July 22, 2020 6:38:52 PM

REMARKS PRESENTED TO CDC FORUM
Guidelines for Prescribing Opioids for the Management of Chronic Pain
July 22, 2020

I am Scot Faulkner with the Photobiomodulation Foundation.

Thank you for this opportunity to offer suggestions on updating and expanding the CDC's Guidelines for Prescribing Opioids for the Management of Chronic Pain.

The Foundation endorses your more holistic approach by placing opioid use into a broader set of options for managing pain. We also endorse the nonopioid treatment recommendations highlighted on Dr. Christina Mikosz's Slide 23.

These nonopioid treatments should include Restorative Therapies as outlined in the Department of Health and Human Services, "Pain Management Best Practices Inter-Agency Task Force Report issued on May 9, 2019.

On September 20, 2019, that report's holistic approach was validated in the Centers for Medicare and Medicaid Services (CMS) Action Plan to Prevent Opioid Addiction.

Both reports outlined how prescribing opioids should be part of a broader, integrated, approach for pain management.

There are many Restorative Therapies that have proven effective in pain management, either as standalone treatments or adjunctive to opioids. These should be considered by this Board.

One of these therapies is Photobiomodulation (PBM).

PBM Therapy's efficacy is supported by over 700 Randomized Clinical

Trials (RCTs) and 6,000 research studies, many published in leading scientific journals. There have been 100 million successful patient treatments without any documented side effects.

PBM is FDA cleared.

PBM is red and near infrared light. When directed at the parts of the body with the right intensity, PBM stimulates mitochondria to repair and restore cell functions and reduce inflammation. It is a natural process aiding a natural process.

The Multinational Association of Supportive Care in Cancer (MASCC) established PBM Therapy as the Standard of Care for treating pain and side effects relating to cancer chemotherapy and stem cell transplants. The Academy of Laser Dentistry (ALD) includes PBM therapy in their Standard of Care for treating pain and reducing opioid use during oral surgery.

PBM is being used in Veterans Hospitals for reducing opioid use in pain management.

Please incorporate Restorative Therapies as part of your broader pain management focus when updating and expanding the CDC guidelines and your public awareness materials.

Thank you.

Hon. Scot Faulkner
Photobiomodulation (PBM) Foundation
www.CongressPBM.com
https://www.PBMFoundation.org

Photobiomodulation Therapy (PBM Therapy),
previously known as Low-Level Laser Therapy (LLLT), is a low intensity visible and near-infrared light therapy which is applied to joints, injuries and the nerves that supply them [1]. The effects are analgesic, anti-inflammatory and regenerative (the light improves the rate of tissue healing) [2]. PBM Therapy is usually applied multiple times a week for several weeks, which leads to substantial relief. There is significant evidence from over 700 RCTs, and systematic reviews that show benefits of PBM Therapy is effective for musculoskeletal [3-5], neuropathic [6], and reduces the need for opioids by managing pain [7]. The treatments are safe [8] and noninvasive [9]. It is recommended for preventing oral mucositis and other side-effects of chemotherapy [10].

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Broken Promises: Chronic Pain Care In Our Own Words

Terri A Lewis, PhD, NCC

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Submission to Docket No. CDC-2020-0029 2020-08127

Jun 16, 2020 Comment Tracking Number: 1k4-9ha9-uker

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About This Survey Experience

Administration

In the spring of 2016, FDA hosted a meeting for the purpose of addressing the use of opioid medications by persons with chronic pain. In preparation for this event, I developed a survey to allow individuals who were incapable of traveling due to illness, time and lack of financial resources to submit their comments in response to a set of specific questions. By the meeting date, more than 1,600 persons had responded. After the meeting, as awareness grew, a number of individuals and their care partners requested that they too be able to share their comments. I kept the survey collector open to allow individuals across the nation to share their experiences. By December 30, 2019, the volume of responses had grown to N 4,535 submissions, at which time I closed the survey collector and began an earnest analysis of submitted comments across time.

Distribution. The collector was distributed throughout social media platforms – facebook, twitter, email links, Instagram and more. Participants in this process were deidentified. Snowball sampling was utilized to develop a snapshot of people navigating changes to healthcare. This opportunistic sampling method has inherent limitations – penetration of the instrument depended on the availability of digital tools, internet access, and in some cases, the support of friends, family and caregivers. Responses were drawn from every state in the union and two US territories – Puerto Rico and the Virgin Islands. Where some states have limited population and lack widespread broadband the response was less. Urban areas had a more robust response. The number of responses obtained overcame limitations of penetration.

Analysis. Thirty questions were developed that focused on the following issues: (1) Demographics; (2) Syndromes, Disorders, Signs and Symptoms associated with reportable multiple chronic conditions for which opioids were used to palliate chronic and/or intractable pain; (3) Pharmacy and polypharmacy limitations arising out of changes to guidance and regulations from 2016 forward; (4) Sequelae that accrued to users of health services due to changes arising from CDC guidance and federal and state regulations including - discontinuation of medications, abandonment by treatment providers, step therapy, changes to treatment protocols, involuntary taper from stable routines, suicide, and death that accrued from destabilization or changes to routines of care; and (5) Identification of insurmountable barriers imposed by changes to CDC guidance, and state and federal regulations. Results were analyzed contextually to build a glossary for each question and to identify trends and themes. Qualitative analysis was used to extract patterns and relationships between the identifiable variables. Quantitative analysis was applied to results of each question using SPSS.

Included in this submission to CDC is a brief summary of the reported experience of 4635 individuals (children – elderly) who live with daily chronic or intractable pain. The majority of them meet the definition of serious chronic illness, have multiple, progressive comorbidities that have been challenging for a long time. Responses include the voices of caregivers who responded on behalf of their loved ones and responses from persons who deceased after they submitted on their own behalf. Health care providers also submitted comments in their roles as clinical helpers.

This is the story of a nation experiencing two sequelae associated with the publication of the CDC Guidelines for Opioid Prescribing for Chronic Pain (2016) – broken healthcare promises and an excessive burden of unpalliated pain.

Section I. Demographics

Table 1. Respondent role

Q1	My role is (select your primary role)-	Responses	
	Answer Choices	%	n
a	Person with chronic pain	95.02%	4403
b	Care partner to someone with chronic pain	1.77%	82
c	Family member of a person with chronic pain	2.74%	127
d	Helper (other friend, neighbor, health care provider)	0.47%	22
e	Comments		1536
		Answered	**4634**
		Skipped	0

Person with chronic pain

"I suffer from pain related to a slipped (subluxated close to 40%) L3 over L4 with a severe herniated disc, as well due to this condition spine at this site tends to float which causes a whole host of conditions. I have constant muscle spasms all throughout my thoracic area. I also suffer with DDD, spondylosis, spinal stenosis, sciatica, random numbing in different areas of my body. Without medication my pain level ranges from around 7 at rest, to 9 when active. With correct medications my pain levels were maintained around 2 and 4 respectively. I was with one pain management doctor for over 5 years and it took a while to find the correct correlation of medications to bring my pain levels down. We hit the jackpot with Hysingla 20mg/day and Hydrocodone 10/325x5/day. I was unable to use anything stronger due to my being stuck on Medicaid, long story. Since this whole "Opioid Crisis" blew up Medicaid changed their list of preferred medications and removed the Hysingla and they wanted me to go through the whole process of trial and fail again to get it back. They tried Tramadol ER 200mg/day which made me so sleepy I could not function. Then the PM doctor decided to try Butrans 15mcg/wk (Buprenorphine) and had I known then what I know now about Buprenorphine I would have refused, because of its effects on opioid receptors I lost over 90% of the pain and analgesic effects from the Hydro causing more breakthrough pain than I have ever had. Long story short I had a colonoscopy done 2 days before my pain management appointment and due to the medications I was on, they used Fentanyl in the anesthesia which, of course, caused me to test positive for Fentanyl on my UDS. PM did not contact me right away with these results to determine why or how. They sat on it until my next appointment and since I was unaware that Fentanyl was used during my colonoscopy when they confronted me with the UDS results needless to say I was taken aback in the extreme. Add to that I was near my minimum on my count for the Hydro due to the Buprenorphine blocking their effects. I was accused of illicit use of Fentanyl and cut from pain management with only 40 Hydro to taper with. I was also given a list of treatment centers etc... and I can tell you that I have never used anything illicitly since I was 15 and the only thing I have ever been addicted to is not being in pain. I had to go through 5 calls to PM Dr.'s all of which refused to see me and their only excuse was because I had already been release from one PM Dr. regardless of the reason. It took the help of my PCP, who is the best doctor that I have ever had, to help me get in with another PM Dr. but I am still a week out from that and it has been nearly 2 months of agony getting just to this point. I can tell you without a doubt from all my own research that the governments, FDA, DEA, the media, and many others have overblown this whole "Opioid Crisis" and have *misapplied the CDC MME guidelines in the extreme."* (D.B., Male, 56 yrs old, Springdale, Arizona)

Care partner to a family member with pain

I'm a caregiver for a chronic pain patient. This was his letter explaining his disorders. He is not a candidate for surgery.

"Before the CDC guidelines I was on pain medication for the following problems. Ankylosing Spondylosis of Spine. Osteoarthritis of the knee and spine, significant effacement of the CSF. Bilateral Foraminal Stenosis, Foraminal nerve root impingement, lumbar scoliosis and torn meniscus. Degenerative Disk Disease. I had been with a pain management specialist for 12 years. I was a 100% compliant patient. After the CDC guidelines came out I was concerned. I was told, don't worry, the guideline is just for general practitioners. You see a Pain Management Specialist. You are protected. That was until December of 2016. I was told because of the CDC guideline, and the Surgeon General Letter; Medicare was reducing the amount of medication my doctor could prescribe from 170 to 120. There began a rapid withdraw of medication. I am on one quarter of what I was 1 Jan 2016. I am holding out hope that someone will help us." (D.E., 52 yrs old, Springfield, VA)

Family member of a loved one with pain
"My mom was in pain and having an anxiety attack from it after her hip replacement left her with chronic hip pain. My sister took her to the hospital, they sent her out barely paying any mind. She had a heart attack alone at her apartment that night." (L.S. Denver, Colorado)

Child care partner to a parent in pain
"My mother has dopamine responsive dystonia. In 2005, when I was 6 years old, my mother was diagnosed with the illness by a university hospital movement disorder center. It has progressively gotten worse over the years. My mom cannot get out of bed or walk. She was dropped from her doctor. Stopping medication isn't good for her. Most of the pain management places will not except certain insurances or they are crowded because so many other clinics refuse to take them. My dad left us. I have been her care giver my whole life." (A.M., Houston, TX)

Helper
"I am the only Family Practitioner in my area that openly treats chronic pain patients without discrimination. All other providers refuse to treat Oregon Health Plan patients in chronic pain, but turn around and treat their patients with commercial insurance and the exact same medical condition with opiates. They are not treating the pain, but the insurance plan for the money!" (Dr. D.G. Roseburg, OR)

Testimony of a deceased survey respondent
"I am pretty much home bound. Only go out to appointments. I used to be so independent and it made my moral to live high. I am now back in a wheelchair. I don't even have a wheelchair ramp. I didn't need one until you guys felt opiates was a crisis. No doctor in Indiana will write prescriptions for opiates any longer. They are pushing drugs that caused me to almost die, or have the steroid injections which I have scar tissue in my epidural space because I have had so many. Allow me to get back to my medical regime that included MSER, that gave me a productive and functioning life. I could get rid of the nurse, clean my whole house, cut my grass. grow my garden that has been empty for 2 years. I am an amputee but could walk with prostheses without pain. Presently I get pain relief for an hour after taking Morphine IR at a small dose." (D.A. 51 yrs old, Portage, Indiana stopped eating, drinking after abandonment)

A parent on behalf of a child in pain
"I have two children with inherited pancreatitis and both have Type 3 diabetes, PTSD, anxiety. Their father died from the same condition. My children's pain is not expected to subside. We are not having luck with alternative, less aggressive treatments. I want them to have access to all medications. I've noted medications above that I believe we will need access to in the near future." (E.S., North Dakota)

Respondent characteristics

Table 25. Respondent Age Grouping

Q25	Which category below includes your age?	Responses	
	Answer Choices	%	n
a	17 or younger (Parent disclosure on behalf of child)	0.32%	16
b	18-20	0.15%	7
c	21-29	2.52%	117
d	30-39	10.64%	493
e	40-49	21.57%	1000
f	50-59	33.44%	1550
g	60 or older	31.35%	1453
		Answere	**4635**
		Skipped	0

Table 26. Respondent reported sex, gender

Q26	What is the sex or gender orientation you declare?	Responses	
	Answer Choices	%	n
a	Female	77.39%	3587
b	Male	21.34%	989
c	Other gender orientation (LGBTQ)	0.80%	37
d	Do not choose to declare	1.17%	54
e	Do you believe that sex or gender is a factor in the quality of your care?		2937
		Answere	**4616**
		Skipped	0

Table 27. Self-reported racial, ethnic group

Q27	Racial or ethnic group with which you identify for census purposes	Responses	
	Answer Choices	%	n
a	Caucasian	95.43%	4383
b	African American	1.44%	66
c	Hispanic or Latina	2.70%	124
d	Asian Pacific Islander	0.33%	15
e	Asian subgroup	0.52%	24
f	Native American	3.37%	155
		Answere	**4593**
		Skipped	42

Table 28. Self-reported educational attainment

Q28	Highest level of education (Select one).	Responses	
	Answer Choices	%	n
a	High school or GED	14.59%	675
b	Some college	28.91%	1337
c	Community College or Trade School Training	22.38%	1035
d	4 year College degree	20.91%	967
e	Master's degree or work toward Master's degree	14.36%	664
f	Doctoral degree or equivalent work towards degree (includes PhD, JD, MD, or combination)	4.32%	200
g	Other	4.26%	197
h	Do you manage your health care independently, or do you rely on a friend or advocate to assist you with your medical interactions? If you rely on a friend or advocate, do your health care providers accept their presence, assistance, or advocacy?		3522
		Answere	**4625**
		Skipped	10

Table 20. Household income by source

Q20	Select all sources for your household income or the household income available to the person you are assisting.	Responses	
	Answer Choices	%	n
a	I have no personal contribution to household income to report	13.72%	636
b	Wages, earned income	28.31%	1312
c	VA Disability	3.73%	173
d	Social Security Disability (SSDI)	43.09%	1997
e	Social Security Insurance (SSI)	10.74%	498
f	Social Security Retirement (SSA)	12.13%	562
g	Pension	11.91%	552
h	Private Insurance Disability from employer	5.98%	277
i	Savings	15.08%	699
j	Trusts	1.38%	64
k	Other (if other, add source to comments)	5.76%	267
l	Other (please specify)	25.50%	1182
		Answere	**4635**
		Skipped	**0**

Where do respondents live?

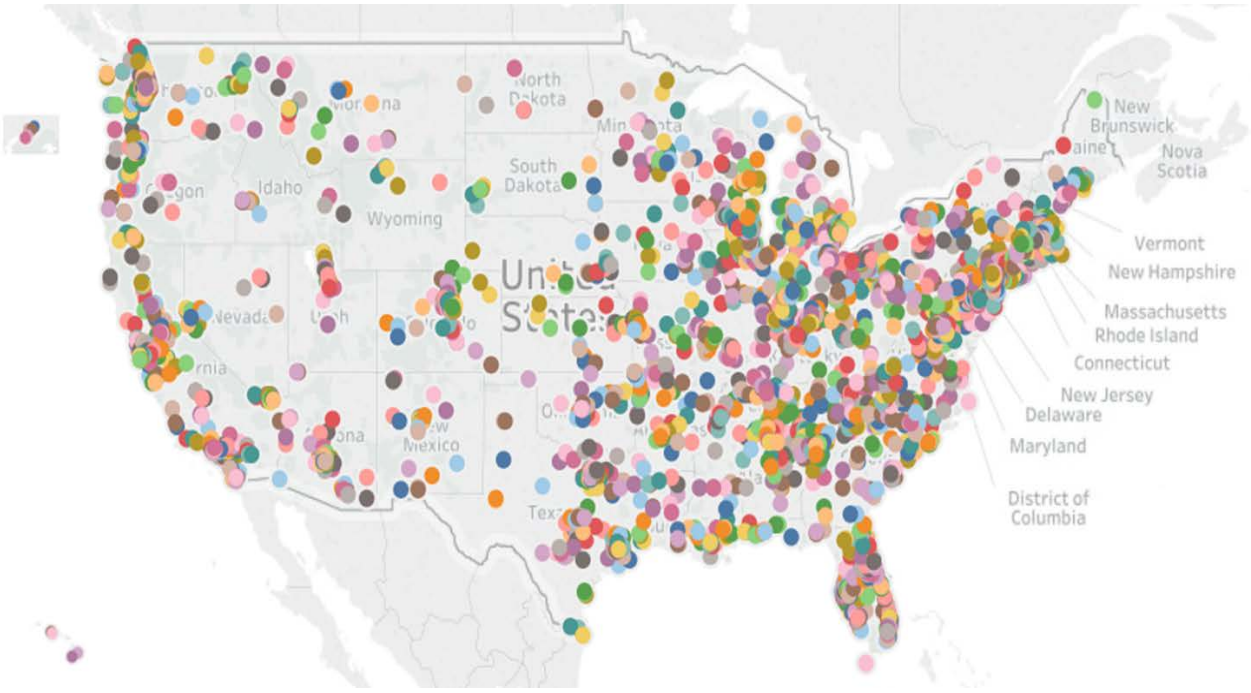

Figure Q1 – Map of Respondents by State (See Table Q1)

Table 24. Demographics

Q24	Demographics (REQUIRED)	Responses	
	Answer Choices	%	n
a	Number Respondents	100.00%	4635
b	**Number respondents deceased after submitting to survey results**		**2**
c	Cities represented	99.81%	2731
d	Metropolitan statistical areas represented		894
e	States, territories represented	99.81%	52
f	ZIP codes:	100.00%	3515
g	Congressional Districts		3225
h	Valid contact email Addresses:	100.00%	4635
		Answered (N)	**4635**
		Skipped	0

Table Q1. Respondents by Geographic Distribution				Gender		
State	No. Respondents	No. Cities	No. Zip Codes	M	F	O
AK	23	9	11	7	16	0
AL	86	57	74	25	61	0
AR	69	48	54	21	46	2
AZ	160	54	104	28	131	1
CA	353	203	272	61	289	3
CO	112	42	72	21	91	0
CT	46	36	40	7	39	0
DC	2	1	1	0	2	0
DE	11	8	9	1	10	0
FL	338	151	237	63	275	4
GA	109	76	90	36	73	2
HI	9	5	6	1	8	0
IA	38	27	30	11	27	0
ID	28	17	23	0	28	1
IL	126	92	106	27	99	2
IN	115	74	92	20	95	1
KS	40	25	31	9	31	0
KY	39	26	31	9	30	0
LA	57	37	42	18	39	0
MA	84	66	72	17	67	2
MD	78	52	60	15	63	3
ME	34	27	28	10	24	0
MI	209	131	155	44	165	3
MN	65	44	52	18	47	0
MO	106	70	79	17	89	1
MS	41	29	34	18	23	0
MT	42	21	29	10	32	0
NC	136	80	107	28	108	0
ND	9	7	8	3	6	0
NE	29	21	25	7	22	0
NH	33	22	25	4	29	1
NJ	79	65	61	12	67	0
NM	39	18	27	9	30	1
NV	61	19	57	11	50	0
NY	157	111	132	39	118	3
OH	174	101	134	45	129	0
OK	92	49	66	17	75	0
OR	136	58	77		136	1
PA	194	133	148	43	151	1
PR	1	1	1	0	1	0
RI	12	8	9	2	10	0
SC	67	47	54	19	48	0
SD	10	9	10	0	10	0
TN	144	78	106	26	118	0
TX	277	152	220	66	211	3
UT	53	29	34	16	37	0
VA	145	85	108	37	108	2
VI	1	1	1	0	1	0
VT	9	7	6	6	3	0
WA	195	90	133	23	172	0
WI	101	66	81	15	86	0
WV	41	23	28	7	34	0
WY	19	14	14	6	13	0

Section II. Syndromes, Disorders, Signs and Symptoms

What is a chronic disease?

In adulthood, a chronic disease has the following key features: Duration (length of time); course (progression, recurrence, or steady state); lack of reversibility (symptoms and pathological alterations of body systems); need for treatment (pharmacological, nonpharmacological, care setting); and consequences (increasing disability, reduced quality of life, disease burden, and more). Chronicity across morbidities is variable and unique to the affected individual, but shares the features of prolonged duration and worsening disability and quality of life. It requires a long period of intervention, treatment or rehabilitation.

Assessing and Measuring Chronic Multimorbidity in the Older Population: A Proposal for Its Operationalization
J Gerontol A Biol Sci Med Sci, 2016, Vol. 00, No. 00, 1–7
doi:10.1093/gerona/glw233

In childhood, chronic health conditions (both chronic illnesses, chronic physical disabilities, and sequelae of injury) are generally defined as those conditions that last > 12 months and are severe enough to cause abnormal growth and development and frequent pain or discomfort; create some limitations in expected developmental activities of childhood like school and peer activities; and may require frequent hospitalizations, outpatient visits, and medical treatments. The impact may persist into adulthood.

DM Consolini MD (2020, Mar) Children with chronic health conditions
https://www.msdmanuals.com/professional/pediatrics/caring-for-sick-children-and-their-families/children-with-chronic-health-conditions

What are multiple chronic conditions (MCC)

"Chronic conditions are conditions that last a year or more and require ongoing medical attention and/or limit activities of daily living. They include both physical conditions such as arthritis, cancer, and HIV infection. Also included are mental and cognitive disorders, such as ongoing depression, substance addiction, and dementia. MCC are concurrent chronic conditions. In other words, multiple chronic conditions ('multi morbidity') are two or more chronic conditions that affect a person at the same time. For example, either a person with arthritis and hypertension or a person with heart disease and depression, both have multiple chronic conditions."

US Department of Health and Human Services, (nd)

What is multimorbidity?

"Multimorbidity is defined as any combination of chronic disease with at least one other disease (acute or chronic) or biopsychosocial factor (associated or not) or somatic risk factor. Any biopsychosocial factor, any risk factor, the social network, the burden of diseases, the health care consumption, and the patient's coping strategies may function as modifiers (of the effects of multimorbidity). Multimorbidity may modify the health outcomes and lead to an increased disability or a decreased quality of life or frailty."

JY Le Reste, P Nabbe, B Manceau, et al (2013).
The European General Practice Research Network Presents a Comprehensive Definition of Multimorbidity in Family Medicine and Long Term Care, Following a Systematic Review of Relevant Literature,
Journal of the American Medical Directors Association, 14(5), 319-325,

What is a rare disease and how is it classified in the USA?

"In the United States, a rare disease is defined as a condition that affects fewer than 200,000 people in the US. This definition was created by Congress in the Orphan Drug Act of 1983. Rare diseases became known as orphan diseases because drug companies were not interested in adopting them to develop treatments. The Orphan Drug Act created financial incentives to encourage companies to develop new drugs for rare diseases. The rare disease definition was needed to establish which conditions would qualify for the new incentive programs.

There may be as many as 7,000 rare diseases. The total number of Americans living with a rare disease is estimated at between 25-30 million. This estimate has been used by the rare disease community for several decades to highlight that while individual diseases may be rare, the total number of people with a rare disease is large. In the United States, only a few types of rare diseases are tracked when a person is diagnosed. These include certain infectious diseases, birth defects, and cancers. It also includes the diseases on state newborn screening tests. Because most rare diseases are not tracked, it is hard to determine the exact number of rare diseases or how many people are affected."

National Center for Advancing Translational Sciences,
Genetic and Rare Disease Information Center
National Institute of Health

What is the International Classification of Disease (WHO-ICD)?

In WHO's international classifications, health conditions (diseases, disorders, injuries, etc.) are classified and defined primarily in the International Classification of Diseases, Tenth Revision (ICD-10), which provides an etiological taxonomy and framework. ICD-10 provides a "diagnosis" of diseases, disorders or other health conditions, and this information is enriched by the additional information given by ICF on functioning.

Functioning and disability associated with health conditions are classified in ICF. ICD-10 and ICF are therefore complementary, and users are encouraged to utilize these two members of the WHO family of international classifications together. Together, information on diagnosis plus functioning provides a broader and more meaningful picture of the health of people or populations, which can then be used for decision-making purposes."
International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Vols. 1-3. Geneva, World Health Organization, 1992-1994.

What is the International Classification of Functioning (WHO-ICF)?

"The overall aim of the ICF classification system is to provide a unified and standard language and framework for the description of health and health-related states. It defines components of health and some health-related components of well-being (such as education and labor). The domains contained in ICF can, therefore, be seen as health

domains and health related domains. These domains are described from the perspective of the body, the individual and society in two basic lists: (1) Body Functions and Structures; and (2) Activities and Participation.

As a classification, ICF systematically groups different domains for a person in a given health condition (e.g. what a person with a disease or disorder does do or can do). Functioning is an umbrella term encompassing all body functions, activities and participation; similarly, disability serves as an umbrella term for impairments, activity limitations or participation restrictions. ICF also lists environmental and community factors that interact with all these constructs. In this way, it enables the user to record useful profiles of individuals' functioning, disability and health in various domains.

ICF: International Classification of Functioning, Disability and Health Geneva, World Health Organization, 2001

What is Systems Medicine?

"… in the current health reform debate, little attention is paid to how medicine is currently taught and practiced. It has long been understood that the fundamental tenets of health arise from understanding the interaction among genomics, the external environment, and behavior. Modern medicine often neglects this comprehensive model and treats disease in isolation, without taking into account the dynamic, integrative systems in the human body. Proponents of a new approach in medical education and practice look toward "systems medicine," which incorporates the complex biochemical, physiological, and environmental interactions that sustain living organisms. Although a holistic approach to medicine should benefit patients and society, consideration of the sociolegal, ethical, and economic implications is essential."

Federoff HJ, Gostin, LO. Evolving From Reductionism to Holism: Is There a Future for Systems Medicine? *JAMA.* 2009;302(9):994–996. doi:10.1001/jama.2009.1264

What is Medical Necessity?

Medical necessity is a legal concept which refers to the health care services or products provided by a physician to a patient. It is provided for the purpose of preventing, diagnosing, treating an injury or disease in accordance with generally accepted standards of medical practice. According to Medicare.gov, the term *medically necessary* is defined as "health-care services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine." In any of those circumstances, if your condition produces debilitating symptoms or side effects, then it is also considered medically necessary to treat those. Medicare defines "*medical necessity*" as services or items reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Table 4. Disease characterization (acute, chronic, intractable, onset, progression)

Q4	Characterize your disease and pain symptoms in terms of the length of time that you have been dealing with it. Select the answer that best applies to you.	Responses	
	Answer Choices	%	n
a	Less than 90 days (acute)	0.11%	5
b	More than 90 days (chronic/intermittent)	1.34%	62
c	More than 90 days (chronic/intractable and always present)	19.92%	923
d	I was identified with one or more of these conditions from childhood (before the age of 18 years)	4.96%	230
e	These conditions are not expected to cure and will need to be managed for the rest of my life (palliative care)	68.06%	3154
f	The diseases that generate my pain are progressive and will eventually require end-of-life (hospice care)	5.61%	260
g	Identify the year you began to receive treatment for chronic or intractable pain associated with your health condition(s) or the point that it began to interrupt your activities of daily living.		4634
		Answered (N	**4634**
		Skipped	0

Legitimate Medical Purpose

(a) A prescription for a controlled substance to be effective must be issued for a *legitimate medical purpose* by an *individual practitioner* acting in the *usual course of his professional practice*. The *responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner*, but a *corresponding responsibility rests with the pharmacist who fills the prescription*. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of *section 309 of the Act (21 U.S.C. 829)* and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 U.S. Code, Chapter II, §1306.04 Purpose of issue of prescription

The ICD10: Syndromes, Disorders, Signs and Symptoms

Table Q3-A Frequency of self-reported diagnoses

ICD-10 Body System	*No.**
I. Certain infectious and parasitic diseases	731
II Neoplasms	395
III Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	217
IV Endocrine nutritional and metabolic diseases	1032
V Mental and behavioral disorders	1149
VI Diseases of the nervous system	13966
VII Diseases of the eye and adnexa	81
VIII Diseases of the ear and mastoid process	67
IX Diseases of the circulatory system	549
X Diseases of the respiratory system	101
XI Diseases of the digestive system	797
XII Diseases of the skin and subcutaneous tissue	398
XIII Diseases of the musculoskeletal system and connective tissue	16001
XIV Diseases of the genitourinary system	355
XV Pregnanacy, childbirth and the puerperium	
XVI Certain conditions originating in the perinatal period	14
XVII Congenital malformations, deformations and chromosomal anomalies	648
XVIII Symptoms, signs and abnormal laboratory findings not elsewhere classified	3988
XIX Injuries, poisonings, other consequences of external causes	4235
XX External causes of morbidity and mortality	2025
XXI Factors influencing health status and encounters with health services	

*Number of extracted, unique diagnostic references assigned to ICD subcategory

Table Q1,3,4 Rare diseases with links

Code	Self-reported search term	Rare disease information link (Orphanet, NORD, GARD)
A15.0	Tuberculosis	ORPHA:3389 Tuberculosis
A49	Mycoplasma*	ORPHA:83482 Mycoplasma encephalitis
A69.20	Lyme (Borellia)*	ORPHA:91546 Lyme disease
A77	Rocky Mountain Spotted Tick Fever	ORPHA:83595 Colorado tick fever
A77.4	Ehrlichiosis	ORPHA: 1902 Erlichiosis
A86	Viral encephalitis	ORPHA:97275 Encephalitis
A93	Colorado Tick Fever	ORPHA:83595 Colorado tick fever
B00	Herpes*	ORPHA:1930 Herpes simplex virus encephalitis
B02.2	Post herpetic trigeminal neuralgia (TMJ)	ORPHA:221091 Trigeminal neuralgia
B10	Epstein barr virus*	ORPHA:2566 Chronic Epstein-Barr virus infection syndrome
B18.1	Hepatitis B	ORPHA:562639 Primary biliary cholangitis/primary sclerosing cholangitis and autoimmune hepatitis overlap syndrome
B18.8	Hepatitis	ORPHA:402823 Hepatitis delta
B20	HIV*	ORPHA:443291 HIV-associated cancer
B25	Hepatitis C	ORPHA:284102 hepatitis C
B44.0	Aspergillosis*	ORPHA:1163 Aspergillosis
B58	Toxoplasmosis*	ORPHA:2518 Autosomal recessive chorioretinopathy-microcephaly syndrome
B60	Babesiosis	ORPHA:108 Babesiosis
B78.9	Strongyloidiasis	ORPHA:76 (Disorder) Strongyloidiasis
C17	Lynch Syndrome (cancer of small intestine)	ORPHA:144 (Disorder) Lynch syndrome
C25.9	Pancreatic cancer	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (2 variants)
C34.90	Lung cancer	ORPHA:70573 Small cell lung cancer
C43.9	Melanoma	ORPHA:252206 Melanoma
C44.92	Squamous cell carcinoma	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (24 variants)
C50.919	Breast cancer	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (4 variants)
C56.9	Ovarian cancer*	ORPHA:213500 Ovarian cancer
C64.9	Kidney cancer, unspecified	ORPHA:217071 (Group of disorders) Renal cell carcinoma
C67.9	Bladder cancer	ORPHA:284400 Small cell carcinoma of the bladder
C72.9	Central nervous system tumors (brain, spinal cord, nerves)	ORPHA:251870 Central nervous system embryonal tumor
C73.0	Thyroid cancer	ORPHA:142 Anaplastic thyroid carcinoma
C81	Non-Hodgkins's Lymphoma	ORPHA:300846 Aggressive B-cell non-Hodgkin lymphoma (8 variants)
C90	Multiple Myeloma	ORPHA:29073 Multiple myeloma
C91	Lymphoid leukemia	ORPHA:67038 (Disorder) B-cell chronic lymphocytic leukemia
C92	Chronic myeloid leukemia	ORPHA:521 (Disorder) Chronic myeloid leukemia
C95	Leukemia*	ORPHA:513 Acute lymphoblastic leukemia (60 variants)
C96.2	Mast cell leukemia*	ORPHA:98851 (Disorder) Mast cell leukemia
D16.9	Osteomas*	ORPHA:352540 Oncogenic osteomalacia
D18	Hemangioma	ORPHA:458775 Congenital hemangioma
D36.1	Neuroma*	ORPHA:251992 Ganglioneuroma
D45	Polycythemia Vera	ORPHA:729 Polycythemia vera
D47.Z2	Castleman disease (Angiofollicular lymph node hyperplasia)	ORPHA:160 (Disorder) Castleman disease
D50	Iron deficiency anemia	ORPHA:209981 (Disorder) IRIDA syndrome
D53.0	Protein S deficiency	ORPHA:26349 (Disorder) Protein S acquired deficiency
D53.1	Megaloblastic Anemia	ORPHA:319651 (Disorder) Constitutional megaloblastic anemia with severe neurologic disease
D55.0	G-6-PD deficiency	ORPHA:466026 Class I glucose-6-phosphate dehydrogenase deficiency
D56	Thalassemia	ORPHA:846 Alpha-thalassemia
D57.	Sickle cell disorders	ORPHA:251380 fetal hemoglobin-sickle cell disease syndrome
D59.2	**Atypical hemolytic uremic syndrome**	ORPHA:2134 (Disorder) Atypical hemolytic uremic syndrome
D61.1	**BoneMarrowSuppression, Aplastic Anemia**	ORPHA:182040 (Group of disorders) Aplastic anemia
D64.9	Anemia*	ORPHA:101096 Aregenerative anemia
D68.0	Antiphospholipid antibody syndrome (APS)*	ORPHA:398097 Neonatal antiphospholipid syndrome
D68.2	Platelet Factor V deficiency	ORPHA:326 Congenital factor V deficiency
D68.4	Hemophilia B, acquired	ORPHA:98879 (Disorder) Hemophilia B
D68.61	Antiphospholipid syndrome (Lupus)	ORPHA:464343 (Disorder) Catastrophic antiphospholipid syndrome
D69.6	Thrombocytopenia	ORPHA:444463 (Disorder) Autoimmune hemolytic anemia-autoimmune thrombocytopenia-primary immunodeficiency syndrome
D70.1	Agranulocytosis	ORPHA:99749 (Disorder) Kostmann syndrome
D86.0,1,2,3,8,9	Sarcoidosis*	ORPHA:797 Sarcoidosis
D89.40	Mast Cell Activation Disorder*	ORPHA:2467 Systemic mastocytosis
D89.40	Autoimmune disorder, unspecified	ORPHA:519264 Inflammatory/autoimmune disorder involving the lacrimal system

Table Q1,3,4 Rare diseases with links

Code	Self-reported search term	Rare disease information link (Orphanet, NORD, GARD)
E03.9	Hypothyroidism*	ORPHA:226298 Central congenital hypothyroidism
E05	Graves Disease*	ORPHA:525731 Pediatric-onset Graves disease
E07	Thyroid disease unspecified	ORPHA:142 Anaplastic thyroid carcinoma
E08-E13	Diabetes mellitis due to underlying condition	E08.9, E09.9, E13.9
E14	Diabetes , unspecified	ORPHA:101952 Rare diabetes mellitus
E20.9	Hypoparathyroidism	ORPHA:36913 Autoimmune hypoparathyroidism
E21.9	Hypogonadism	ORPHA:174590 (Group of disorders) Congenital hypogonadotropic hypogonadism
E22. 1	Hyperprolactinemia	ORPHA:397685 (Disorder) Familial hyperprolactinemia
E24.9	Cushing's Syndrome	ORPHA:99892 (Group of disorders) ACTH-dependent Cushing syndrome
E27. 5	Pheochromocytoma	ORPHA:573163 (Group of disorders) Pheochromocytoma-paraganglioma
E27.1	Addison's Disease*	ORPHA:85138 Addison disease
E27.1	Adrenal insufficiency [chronic primary adrenal insufficiency (CPAI)]*	ORPHA:101963 (Group of disorders) Acquired chronic primary adrenal insufficiency
E34.9	Lymphedema	ORPHA:568047 (Group of disorders) Disorder with multisystemic involvement and primary lymphedema
E70.0	Phenylketonuria PKU	ORPHA:79254 (Subtype of disorder) Classic phenylketonuria
E70.2	Alkaptonuria/Ochronosis*	ORPHA:56 (Disorder) Alkaptonuria
E72.1	Homocystinuria due to methylene tetrahydrofolate reductase deficiency (MTHFR)*	ORPHA:395 Homocystinuria due to methylene tetrahydrofolate reductase deficiency
E74.12	Fructose Intolerance	ORPHA:469 (Disorder) Hereditary fructose intolerance
E78. 5	Hyper lipidemia	ORPHA:412 (Disorder) Dysbetalipoproteinemia
E80.2	Porphyria *	https://rarediseases.org/rare-diseases/porphyria/
E83.110	Hemochromatosis	ORPHA:465508 (Disorder) Symptomatic form of hemochromatosis type 1
E88	Dercums Disease*	https://rarediseases.org/rare-diseases/dercums-disease/
E88.1	Familial Partial Lipodystrophy*	ORPHA:98306 Familial partial lipodystrophy
E88.4	Mitochondrial myopathy	ORPHA:206966 (Group of disorders) Mitochondrial myopathy
F02.80	Dementia Lewy body	
F03	Dementia, unspecified*	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (32 variants)
F84.0	Autism spectrum disorder	ORPHA:168778 (Group of disorders) Rare pervasive developmental disorder
G02	Meningitis due to fungal infection (1)*	Fungal meningitis outbreak (2012)
G03.9	Adhesive Arachnoiditis*	ORPHA:137817; https://rarediseases.org/rare-diseases/arachnoiditis/
G05	Chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME)*	https://rarediseases.org/rare-diseases/myalgic-encephalomyelitis/
G14	Post polio syndrome*	ORPHA:2942; https://rarediseases.org/rare-diseases/post-polio-syndrome/
G20	Parkinson's Syndrome	ORPHA:171695 (Disorder) Parkinsonian-pyramidal syndrome
G21.0	Neuroleptic Malignant Syndrome NMS (drug induced movement disorder, hyperthermia, Neuroleptic-Induced Acute Dystonia)	ORPHA:94093 (Disorder) Neuroleptic malignant syndrome
G24.9	Dystonia*	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (51 variants); https://rarediseases.org/rare-diseases/dystonia/
G25	Essential Tremor*	https://rarediseases.org/rare-diseases/essential-tremor/
G25.81	Restless leg syndrome*	https://rarediseases.org/rare-diseases/restless-legs-syndrome/
G25.82	Stiff Person Syndrome	ORPHA:443192 (Subtype of disorder) Classic stiff person syndrome
G31.09	Frontal Lobe Dementia	https://rarediseases.org/rare-diseases/frontotemporal-degeneration/
G35	Multiple Sclerosis (MS)*	ORPHA:228145 Multiple sclerosis variant
G37.3	Transverse Myelitis*	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (3 variants)
G37.9	Demyelinating polyneuropathy (CIDP)*	ORPHA:476116 Demyelinating hereditary motor and sensory neuropathy
G40.	Epilepsy*	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (144 variants)
G40.909	SeizureDisorders	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (54 variants)
G44.011	Cluster Headache*	https://rarediseases.org/rare-diseases/cluster-headache/
G47.41	Narcolepsy*	ORPHA:83465 Narcolepsy without cataplexy
G50	Disorders of Trigeminal nerve TMJ	ORPHA:221091 Trigeminal neuralgia
G54	Thoracic outlet syndrome	ORPHA:357131 (Subtype of disorder) Venous thoracic outlet syndrome
G54.5	Parsonage Turner syndrome*	ORPHA:2901 Neuralgic amyotrophy
G56.10	Reflex sympathetIc dystrophy (RSD)*	ORPHA:99994 Complex regional pain syndrome type 2
G57.1	Meralgia paresthetica*	https://rarediseases.info.nih.gov/search?keyword=meralgia%20paresthetica
G57.81	Pudendal neuralgia*	ORPHA:60039 Pudendal Neuralgia
G60	Charcot Marie Tooth Disease (CMT)*	ORPHA:166 Charcot-Marie-Tooth disease/Hereditary motor and sensory neuropathy
G60.0	Hereditary peripheral neuropathy (axonal type)*	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (4 variants)
G60.8	Small fiber neuropathy	
G60.8	Hereditary peripheral neuropathy (axonal type)*	ORPHA:207025 (Group of disorders) Rare hereditary neurologic disease with peripheral neuropathy
G61.0	Guillain-Barre	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (14 variants)

Table Q1,3,4 Rare diseases with links

Code	Self-reported search term	Rare disease information link (Orphanet, NORD, GARD)
G61.81	Chronic inflammatory demyelinating polyneuropathy	ORPHA:2932 (Disorder) Chronic inflammatory demyelinating polyneuropathy
G63	Polyneuropathy	ORPHA:2932 (Disorder) Chronic inflammatory demyelinating polyneuropathy
G70.01	Myasthenia Gravis	ORPHA:589 (Disorder) Myasthenia gravis
G71.0	Muscular dystrophy*	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (86 variants)
G71.3	Mitochondrial Myopathy	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (24 variants)
G90.2	Horner's syndrome-Frankel class*	https://rarediseases.info.nih.gov/diseases/6670/horners-syndrome
G90.4	Autonomic Dysreflexia	
G90.5	Complex Regional Pain Syndrome CRPS/RSD (Causalgia)*	ORPHA:99994 Complex regional pain syndrome type 2; https://rarediseases.info.nih.gov/diseases/4647/complex-regional-pain-syndrome; https://rarediseases.org/rare-diseases/reflex-sympathetic-dystrophy-syndrome/
G91.9	Hydrocephalus*	https://rarediseases.org/rare-diseases/hydrocephalus/
G93. 7	Reye Syndrome	https://rarediseases.org/rare-diseases/reye-syndrome/
G93.2	Pseudotumor cerebrei (intracranial hypertension)*	ORPHA:238624 Idiopathic intracranial hypertension
G95	Syringomyelia*	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (5 variants)
G96.19	Tarlov Cyst*	ORPHA:65250 Perineural cysts
G99.0	Myelopathy*	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (3 variants)
H18.6	Keratoconus*	ORPHA:156071 Keratoconus
H25.9	Cataracts	
H35.30	Macular degeneration*	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (4 variants)
I45.81	Long QT Syndrome*	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (5 variants)
I45.81	Postural Orthostatic Tachycardia Syndrome (POTS)	ORPHA:443236 Postrual Orthostatic Tachycardia Syndrome due to NET
I73	Raynaud's Phenomenon	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (2 variants)
I73.81	Erythromelalgia*	ORPHA:1956 Erythromelalgia
189	Lymphedema*	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (23 variants)
K21.9	Gastroparesis	ORPHA:558411 (Disorder) Idiopathic gastroparesis
K22.0	Achalasia	ORPHA:930 (Disorder) Idiopathic achalasia
K22.7	Barretts esophagus	Esophageal malformation ORPHA:88993
L03.90	Cellulitis	ORPHA:79480 (Disorder) Pemphigus erythematosus
L40.50	Psoriatic arthritis (PsA)	ORPHA:85436 (Disorder) Psoriasis-related juvenile idiopathic arthritis
L40.9	Psoriasis	ORPHA:247353 (Disorder) Generalized pustular psoriasis
L53	Erythema, unspecified	ORPHA:163531 (Group of disorders) Chronic cutaneous lupus erythematosus
L93	Lupus erythematosus	ORPHA:90282 (Disorder) Hypertrophic or verrucous lupus erythematosus
L95	Vasculitis, type unknown	ORPHA:156140 (Group of disorders) Predominantly large-vessel vasculitis ORPHA:156143 (Group of disorders) Predominantly medium-vessel vasculitis ORPHA:156146 (Group of disorders) Predominantly small-vessel vasculitis
L98.49	Skin ulcers	ORPHA:901 (Disorder) Wells syndrome
M05	Other rheumatoid arthritis	ORPHA:47612 (Disorder) Felty syndrome
M06.1	Still's Disease	ORPHA:829 (Disorder) Adult-onset Still disease
M08	Juvenile arthritis	ORPHA:92 (Group of disorders) Juvenile idiopathic arthritis
M22.40	Chondromalacia patellae	ORPHA:1428 (Disorder) Familial chondromalacia patellae
M30.1	Churg Strauss Syndrome	ORPHA:183 (Disorder) Eosinophilic granulomatosis with polyangiitis
M31.30	Wegener's Granulomatosis	ORPHA:900 (Disorder) Granulomatosis with polyangiitis
M31.6	Giant cell arteritis	ORPHA:397 (Disorder) Giant cell arteritis
M32.1	Systematic Erythesthemia Lupus	ORPHA:536 (Disorder) Systemic lupus erythematosus
M33.2	Polymyositis	ORPHA:732 (Disorder) Polymyositis
M34.83	Scleroderma	ORPHA:220402 (Subtype of disorder) Limited cutaneous systemic sclerosis
M35.04	Sjögren's syndrome	ORPHA:289390 (Disorder) Primary Sjögren syndrome
M35.3	Polymyalgia rheumatica	ORPHA:93569 (Disorder) Polymyalgia rheumatica
M35.9	Mixed connective tissue disease (MCTD)	ORPHA:809 (Disorder) Mixed connective tissue disease
M40	Scheuermann's disease	ORPHA:3135 (Disorder) Familial Scheuermann disease
M42.9	Osteochondroma	ORPHA:321 (Disorder) Multiple osteochondromas
M60.9	Focal Nodular Myositis	ORPHA:48918 (Disorder) Focal myositis
M87.0	Avascular necrosis	ORPHA:399164 (Group of disorders) Avascular necrosis
M87.9	Osteonecrosis, bone, unspecified joints	ORPHA:399158 (Group of disorders) Osteonecrosis
N30.20	Chronic Interstitial Cystitis	ORPHA:37202 Chronic Interstitial Cystitis
N32	Other disorders of urinary bladder	ORPHA:84085 (Disorder) Hinman syndrome
Q.05.9	Spina bifida	ORPHA:268388 (Subtype of disorder) Lumbosacral spina bifida aperta ORPHA:268758 (Subtype of disorder) Lumbosacral spina bifida cystica

Table Q1,3,4 Rare diseases with links

Code	Self-reported search term	Rare disease information link (Orphanet, NORD, GARD)
Q06.8	Tethered cord	ORPHA:268861 (Disorder) Primary tethered cord syndrome
Q07.0	Arnold Chiari Malformation, Type I, II or III	ORPHA:268882 (Disorder) Arnold-Chiari malformation type I
Q27.39	AVM (vascular tumor),	ORPHA:211237 (Group of disorders) Rare vascular tumor
Q61.3	Polycystic kidney	ORPHA:730 (Disorder) Autosomal dominant polycystic kidney disease
Q61.5	Medullary sponge kidney*	ORPHA:1309 Medullary sponge kidney
Q62	Congenital defects of ureter	ORPHA:617 (Disorder) Congenital primary megaureter
Q65.89	Hip dysplasia	ORPHA:2114 Hip dysplasia, Beukes type
Q72.90	Leg Length Discrepancy	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (7 variants)
Q74.8	Larsen syndrome	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (7 variants)
Q75.3	Macrocephaly*	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (23 variants)
Q76.1	Klippel Feil Syndrome	ORPHA:2345 (Disorder) Isolated Klippel-Feil syndrome
Q79.6	Ehlers Danlos Syndrome, unspecified	ORPHA:98249 Ehlers Danlos Syndrome (26 variants)
Q79.62	Ehlers-Danlos Syndrome, hypermobile joint type	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (8 Variants)
Q82.0	Meige Syndrome (hereditary lymphedema)	ORPHA:90186
Q85	Neurofibromatosis*	https://www.orpha.net/consor/cgi-bin/Disease_Search_Simple.php?lng=EN (15 variants)
Q87.2	Klippel-trenaunay Syndrome	ORPHA:90308 (Subtype of disorder) Klippel-Trénaunay syndrome
Q87.40	Marfan's Syndrome	ORPHA:284993 (Group of disorders) Marfan and Marfan-related disorders
Q87.8	Campomelia Cumming type	ORPHA:1318 (Disorder) Campomelia, Cumming type

Wrong diagnosis, misdiagnosis leads to wrong care, medical harm

"Conversion disorder can be a misleading diagnosis. In the past, up to 30% of patients diagnosed with conversion symptoms were subsequently discovered to have misdiagnosed organic illness."

https://neuro.psychiatryonline.org/doi/pdf/10.1176/jnp.2010.22.4.451.e13

Differential diagnosis with neurological illnesses is important in such cases, as 6%–30% of these patients are subsequently found to have a medical illness that can account for their symptoms:

Concomitant or previous neurological disorder or a systemic disease affecting the brain was reported in 18% to 64% of cases of conversion disorder.

25%–50% of cases classified as conversion disorder eventually receive diagnoses of neurological or non-psychiatric medical disorders.

A 7- to 11-year follow-up study of 99 patients found that 22 (30%) of 73 available participants had an organic illness accounting for presenting symptoms that were initially diagnosed as conversion disorder.

A 2.5- to 10-year follow-up study of 24 patients discharged from the neuroscience services of a teaching hospital with a diagnosis of conversion disorder found that five (21%) of 24 had a diagnosable neurological disease.

A 6- to 12-month follow-up study of 50 patients discharged from the neurology service of a teaching hospital with conversion in differential diagnosis found that seven (14%) had organic illness and three (6%) had hysterical elaboration of organic pathology. Sixty-four patients with a diagnosis of conversion disorder after psychiatric consultation service were followed for an average of 3.3 years, and eight (13%) had an organic illness. Some of the neurological/medical disorders to be considered in differential diagnosis include many of the diagnosis codes extracted from this list: Dementia and degenerative disorders; Brain tumors, subdural hematoma; Basal ganglia disease, myasthenia gravis, multiple sclerosis; Polymyositis, acquired myopathies; Optic neuritis; Partial vocal cord paralysis; Acquired myopathies; Guillain-Barré, Creutzfeldt-Jakob, periodic paralysis; AIDS (early neurological manifestations); Systemic lupus erythematosus; Idiopathic and sarcoma-induced osteomalacia; Acquired, hereditary, and drug-induced dystonias.

Section III. Sequelae of Outcomes Imposed by Regulatory Changes from 2016

"Palliative care is specialized team care that focuses on improving quality of life for patients and families in the setting of a serious illness. Palliative care is provided by a specially trained team of physicians, nurses, social workers, and others who work together with a patient's other doctors to furnish an added layer of support. Many elements of palliative care—such as skilled communication about what to expect in the future and safe management of pain and other symptoms—can and should be delivered by all frontline clinicians, assuming they have adequate training. *Palliative care is appropriate at any age and any stage in a serious illness*, and it can be provided along with curative treatment. Because palliative care services are based on patient and family need, *not prognosis*, palliative care teams respond to the episodic, complex, and long-term nature of serious illness."

Center to Advance Palliative Care https://www.capc.org/

"As in most high-income nations, health care spending in the U.S. is…concentrated on the sickest and neediest patients: the top 5% of spenders account for nearly 50% of all health care costs. This group is characterized not only by the presence of one or more serious medical illnesses, but also by functional dependency (needing another person to get through the day), cognitive impairment, frailty, and heavy reliance on family and other caregivers. Contrary to common belief, the majority of people in this highest-cost, highest-need group are living with a serious illness (at home). *Only 11% of them are in the last twelve months of life."*

Being Seriously Ill In America Today, October 2018
The Commonwealth Fund, The New York Times
Harvard T.H. Chan School of Public Health

"First, the integration of specialty palliative care services into routine care is increasing. Previously viewed as synonymous only with end-of life care, *palliative care has moved upstream and is increasingly integrated from time of diagnosis throughout the course of serious illness*.[2] The field has experienced considerable growth in the number of consultation teams,[3] outpatient clinics,[4] community-based palliative care models,[5] and medical specialty societies that recommend specialty palliative care involvement.[6] Second, the number of patients with serious illness who are eligible for palliative care services is expected to grow considerably over the next few decades as a result of the rapid growth of the aged population, better understanding of which patients are eligible for palliative care,[7] increasing awareness of the value of specialty palliative care,8 and evolving palliative care consultation triggers and patient identification tools.[9] *Third, deficits in the number of palliative care clinician specialists exist, with gaps estimated in the thousands*.[10]"

Policy Changes Key To Promoting Sustainability And
Growth Of The Specialty Palliative Care Workforce
Arif H. Kamal, Steven P. Wolf, Jesse Troy, Victoria Leff, Constance Dahlin, Joseph D. Rotella, George Handzo, Phillip E. Rodgers, and Evan R. Myers
https: 10.1377/hlthaff.2019.00018 *HEALTH AFFAIRS* 38,(6) (2019): 910–918

The 2019 Final Rule: Broken Promises to Patients with Serious Illness

"***Exempted Beneficiary.*** We proposed that an *exempted beneficiary*, with respect to a drug management program, would mean an enrollee who: (1) Has elected to receive hospice care; (2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or (3) Has a cancer diagnosis. While the first two exceptions are required under CARA, we proposed to exercise the authority in section 1860D– 4(c)(5)(C)(ii)(III) of the Act to treat a beneficiary who has a cancer diagnosis as an exempted individual. We did not propose to exempt additional categories of beneficiaries.

We note that several required features of Part D drug management programs, such as case management, multiple written beneficiary notices, the right to appeal and our general oversight, will serve as beneficiary safeguards should a Part D sponsor inappropriately limit a beneficiary's coverage to frequently abused drugs through a drug management program (p15).

Several commenters suggested that an exemption for beneficiaries who are receiving nonhospice palliative and end-of-life care would be appropriate in light of the exemption for beneficiaries who have elected hospice care. A few of these commenters asserted that without an exemption in the regulation, beneficiaries could be included in a drug management program at a plan sponsor's discretion and experience restricted access to pain-control medication when they need them the most. Some commenters noted that the CDC Guideline exempts patients receiving palliative and end-of-life care. Others disagreed, asserting that we had put sufficient safeguards in place to protect such beneficiaries in drug management programs. Other commenters referred to the difficulty in identifying such beneficiaries in order to exempt them.

Response: We are persuaded that beneficiaries who are receiving nonhospice palliative and end-of-life care but have not elected hospice should be exempted from Part D drug management programs. While we wish to exercise caution and thoughtfulness in establishing regulatory exemptions versus clinical guidelines/criteria, as we noted above, we agree based on the multiple comments that such beneficiaries should be treated the same as beneficiaries who have elected hospice care for purposes of drug management programs, as they are very similar in their health care status, if not their health benefit plan status. While we expect that Part D plan sponsors and PBMs would not inappropriately place such beneficiaries in their drug management programs, an actual regulatory exemption from drug management programs would be more definitive.

Furthermore, adding these exemptions would align the drug management programs with the CDC Guideline, which was developed by experts and specifically provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of life care.

Therefore, for consistency with the CDC Guideline, *beneficiaries who are receiving non-hospice palliative and end-of-life care but who have not elected hospice will be exempted from Part D drug management programs as well*."

CMS Analysis of Proposed Opioid Overutilization Criteria Modifications in Medicare Part D
February 1, 2017
https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Proposed-Opioid-Overutilization-Criteria-Modifications-v-02012017.pdf

Table 22. Self-reported satisfaction with current care protocols

Q22	In the last 24 months, my support for pain management has -	Responses	
	Answer Choices	%	n
a	Improved, gotten better	4.64%	213
b	Stayed about the same with few interruptions	24.37%	1118
c	Gotten worse, with changes or disruptions to my care	54.51%	2501
d	I do not currently have support for pain management	16.09%	738
e	What has made your care better, the same, or worse (please specify)?		2860
		Answered	**4588**
		Skipped	47

"The current medical education system produces insufficient numbers of Pain Medicine specialists to provide advanced-level care for patients with complex issues contributing to pain. The IOM report reflects that there is only one certified Pain Medicine specialist for every 28,500 people with pain. This severe shortage of pain medicine specialists impedes efforts to develop efficient, cost effective health care delivery models for treating the vast population of patients with chronic pain. The lack of research on the most effective clinical pain treatment protocols for specific medical conditions exacerbates this problem…The current system affords insufficient training for primary care physicians in how to most effectively treat pain. State medical boards are working to develop prescribing protocols and CME requirements to address this problem. With the undersupply of competent pain medicine consultation options, primary care physicians often have difficulty referring patients with complex pain problems to specialists. However, states cannot address the undersupply of specialty-level care."

American Board of Pain Medicine
http://abpm.org/

"Geographic location and regional characteristics influence the availability of palliative care services. People living with a serious illness who reside in the northeastern United States have access to significantly more hospital palliative care programs than those living in other regions. The Mid-Atlantic and east north-central regions increased an entire letter grade since 2015, joining New England as "A" regions, with more than 80% of their hospitals now reporting a palliative care team…Access to palliative care for people living in rural America remains limited. Ninety percent of hospitals with palliative care are in urban areas. Only 17% of rural hospitals with fifty or more beds report palliative care programs."

State Report Card 2019
Center to Advance Palliative Care
https://www.capc.org/

Table Q22-A Summary of State Guidelines for Palliative care

State	State	Pain Regulation Link	YR	Palliative care exception	Guidance Language
American Society of Interventional Pain Specialists (ASIPP)	ALL	ASIPP Opioid Prescribing Guidelines	2012		
Center for Disease Control (CDC)	ALL	https://www.cdc.gov/drugoverdose/prescribing/guideline.html	2016	Palliative care exception	This guideline is intended to apply to patients aged ≥18 years with chronic pain outside of palliative and end-of-life care. For this guideline, palliative care is defined in a manner consistent with that of the Institute of Medicine as care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness. Palliative care can begin early in the course of treatment for any serious illness that requires excellent management of pain or other distressing symptoms
Federation of State Medical Boards (FSMB)	ALL	FSMB Opioid Prescribing opioid_guidelines_as_adopted_april-2017_final	2017	Palliative care exception	The guidelines that follow are not intended for the treatment of acute pain, acute pain management in the perioperative setting, emergency care, cancer-related pain, palliative care, or end of life care... It is recommended that prescribers be prepared for risk management with opioids in advance of prescribing amd should use opiate therapy for chronic pain that is noncancer related, or part of palliative care or end of life care only when other non-pharmacological options have not been effective. Maintain opioid doses as low as possible and continue only if clear and objective outcomes are being met.
CFR Hospice	Medicare	https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&rgn=div5&view=text&node=42:3.0.1.1.5&idno=42#se42.3.418_13		Palliative care in hospice rule	*Palliative care* means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.
CMS Multiple Chronic Comorbid Condtions	Medicare	https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/index.html	nd	Multiple chronic comorbid conditions	https://www.hhs.gov/ash/about-ash/multiple-chronic-conditions/index.html and https://www.hhs.gov/ash/about-ash/multiple-chronic-conditions/addressing-multiple-chronic-conditions/index.html#framework
Alabama ADC-540	AL	Alabama Opioid Prescribing Guidelines and https://www.albme.org/csfaq.html https://www.albme.org/riskabusemit.html and Alabama Board of Medical Examiners Risk & Mitigation Strategies	2017	Limited purpose schedule II (LPSP) prescribing protocol 001 Authority Ala Code 20-2-260, Revised: June 21, 2017	For long-acting schedule II controlled substances, the initial dose and any subsequent escalation of the dose must be written by the physician with a CRNP/CNM/PA writing maintenance doses only. Long acting schedule II medications may only be prescribed for patients in Hospice/Palliative care; Nursing home/ rehabilitation facilities; or oncology.
Alaska	AK	Alaska Opioid Prescribing Guidelines	2017		
Arizona	AZ	Arizona Opioid Prescribing Guidelines	2014	Palliative care exception.	These guidelines are not intended to apply to hospice or palliative care patients (as defined in the glossary of terms) or patients with end of life or cancer-related pain. An approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, psychosocial, and spiritual supports.
Californa	CA	California Opioid Prescribing Guidelines	2014	Palliative care exception; Pain Patients Bill of Rights for treatment of intractable pain	Although some of the recommendations in these guidelines might be appropriate for other kinds of pain, they are not meant for the treatment of patients in hospice or other palliative care settings, and are not in any way intended to limit treatment, where improved function is not anticipated and pain relief is the primary goal.
Colorado	CO	Colorado Joint bd policy for prescribing dispensing opioids	2018	Role of palliation addressed	The decision to prescribe or dispense opioid medication for outpatient use may be made only after aproper diagnosis and complete evaluation which should include a risk assessment, pain assessment, and review of relevant PDMP data. These safeguards apply to acute and chronic, non-cancer pain but not to palliative end of life care.
Colorado	CO	Colorado Opioid Prescribing Guidelines	2014	Role of palliation addressed	The decision to prescribe or dispense opioid medication for outpatient use may be made only after aproper diagnosis and complete evaluation which should include a risk assessment, pain assessment, and review of relevant PDMP data. These safeguards apply to acute and chronic, non-cancer pain but not to palliative end of life care.
Connecticut	CT	Connecticut Opioid Prescribing Guidelines	2016	Palliative care exception	The law allows the practitioner to prescribe more than a seven-day supply of an opioid drug to a minor or an adult for first time outpatient use, if in his or her professional judgment, the drug is required to treat the person's acute medical condition, chronic pain, cancer-associated pain, or for palliative care. The practitioner must document the patient's condition in his or her medical record and indicate than an alternative to the opioid drug was not appropriate to treat the patient's medical condition.
Delaware	DE	Delaware Opioid Prescribing Guidelines	2016		
Florida	FL	Florida Opioid Prescribing Guidelines	2016		
Georgia	GA	Georgia Opioid Prescribing Guidelines	2012		
Georgia	GA	Georgia Administrative Board	2013	Palliative care referenced	Any physician who prescribes schedule II or III substances for chronic pain for greater than 50% of that physician's annual patient population must document competence to the board through certification or eligibility for certification in pain management or palliative medicine as approved by the Georgia Composite Medical Board ("Board").
Hawaii	HI	Hawaii Opioid Prescribing Guidelines	2012		
Hawaii	HI	Hawaii Pain Patients bill of rights	2008		
Idaho	ID	Idaho Opioid Prescribing Guidelines	2013		
Illinois	IL	Illinois Opioid Prescribing Guidelines	2016		
Indiana	IN	Indiana Opioid Prescribing Guidelines and http://www.ismanet.org/	2016	Palliative care exception	The rule does not apply to: 1. Patients with a terminal medical condition (refer to definitions section.); 2. Residents of an Indiana licensed health facility (as defined by state law); 3. Patients enrolled in an Indiana licensed hospice program as defined by state law); 4. Patients enrolled in an inpatient or outpatient palliative care program of an Indiana licensed hospital or hospice as defined by state law.
Iowa	IA	Iowa Opioid Prescribing Guidelines	2016	Palliative care referenced	Accepted as specialty medical practice
Kansas	KS	Kansas Opioid Prescribing Guidelines	2016		

Table Q22-A Summary of State Guidelines for Palliative care

Kentucky	KY	Kentucky Opioid Prescribing Guidelines	2003		
Louisiana	LA	Louisiana Opioid Prescribing Guidelines	2017	Incorporates CDC palliative care exception	See CDC Guidelines exception for palliative care
Maine	ME	Maine Opioid Prescribing Guidelines	2016	Palliative care exception	Exceptions to these requirements include 1) when prescribing opioid medication for pain associated with active and aftercare cancer treatment, palliative care, end-of-life and hospice care, and medication-assisted treatment (MAT); and 2) when directly ordering or administering benzodiazepine or opioid medicine to a person in an emergency room setting, an inpaitnet hospital setting, a long term care facility, or a residential facility.
Maryland	MD	Maryland Opioid Prescribing Guidelines	2014	Palliative care exception	The following circumstances are exempted: Opioid prescribed for a substance-related disorder; opioid prescribed for pain associated with a cancem diagnosis; opioid prescribed for pain experienced while the patient is receiving end of life, hospice, or palliative care services; or opioid prescribed for chronic pain
Massachusetts	MA	Massachusetts Opioid Prescribing Guidelines	2015	Palliative care exception	If in the professional medical judgment of a practitioner, more than a 7-day supply of an opiate is required to treat the adult or minor patient's acute medical condition or is necessary for the treatment of chronic pain management, pain associated with a cancer diagnosis , or pain experienced while the patient is in palliative care. The condition triggering the prescription of an opiate for more than a 7-day supply shall be documented in the patient's medical record and the practitioner shall indicate that a non-opiate alternative was not appropriate to address the medical condition.
Michigan	MI	Michigan Opioid Prescribing Guidelines	2016		
Minnesot	MN	Minnesota Opioid Prescribing Guidelines	2016	Hospice exception only	Pursuant to the authorizing statute, the opioid prescribing protocols will not apply to opioids prescribed for patients who are experiencing pain caused by a malignant condition or who are receiving hospice care, or to opioids prescribed as medication-assisted therapy to treat opioid dependency.
Mississippi	MS	Mississippi Opioid Prescribing Guidelines	2016	Incorporates CDC Guidelines by reference	Incorporates CDC Guidelines by reference
Missouri	MO	Missouri Opioid Prescribing Guidelines	2016		
Montana	MT	Montana Opioid Prescribing Guidelines	2009		
Nebraska	NE	Nebraska Opioid Prescribing Guidelines	2016		
Nevada	NV	Nevada Opioid Prescribing Guidelines	2016		These guidelines are not meant for the treatment of patients receiving hospice care, or the treatment of pain and symptom management at the end of life or cancer pain.
New Hampshire	NH	New Hampshire Opioid Prescribing Guidelines	2017	Incorporates CDC and FSMB Guidelines by reference	
New Jersey	NJ	New Jersey Opioid Prescribing Guidelines	2017	Palliative care exception	The law does not apply to a prescription for a patient who is currently in active treatment for cancer, receiving hospice care from a licensed hospice or palliative care, or is a resident of a long term care facility, or to any medications that prescribed in the treatment of substance abuse or opioid dependence (medication assisted treatment).
New Mexico	NM	New Mexico Opioid Prescribing Guidelines	2016		
New York	NY	New York Opioid Prescribing Guidelines	2016	Palliative care confused with hospice care	Effective February 9, 2011, Chapter 331 of the Laws of 2010 (commonly known as the Palliative Care Information Act) amends the Public Health Law by adding section 2997-c, which requires physicians and nurse practitioners to offer terminally-ill patients information and counseling concerning palliative care and end-of-life options. Under the law, information and counseling concerning palliative care and end-of-life options must be offered only to patients with an illness or condition that is reasonably expected to cause death within six months. Palliative care, as defined by the law, is "health care treatment, including interdisciplinary end-of-life care, and consultation with patients and family members, to prevent or relieve pain and suffering and to enhance the patient's quality of life, including hospice care."
North Carolina	NC	North Carolina Opioid Prescribing Guidelines	2017	Palliative care exception	The Board will assume opioid use in such patients is appropriate if the responsible licensee is familiar with and abides by acceptable medical guidelines regarding such use, is knowledgeable about effective and compassionate pain relief, and maintains an appropriate medical record that details a pain management plan. (See the Board's position statement on the Policy for the Use of Controlled Substances for the Treatment of Pain for an outline of what the Board expects of licensees in the management of pain.) Because the Board is aware of the inherent risks associated with effective symptom relief in such situations, it will not interpret their occurrence as subject to discipline by the Board.
North Dakota	ND	North Dakota Opioid Prescribing Guidelines NAMSDL No Board or Pain Guidelines	2016		
Ohio	OH	Ohio Opioid Prescribing Guidelines	2017		
Ohio	OH	http://mha.ohio.gov/Default.aspx?tabid=828	2017	Palliative care law passed 2019	
Oklahoma	OK	Oklahoma Opioid Prescribing Guidelines	2014	Palliative care exception	They are not intended as standards of care or as templates for legislation, nor are they meant for patients in palliative care programs or with cancer pain.
Oregon	OR	Oregon Opioid Prescribing Guidelines	2017		Adoption of CDC Guidelines for Chronic Pain by reference
Pennslyvania	PA	Pennsylvania Opioid Prescribing Guidelines	2016	Palliative care referenced	Palliative care involves the management of symptoms in the setting of any serious illness. The focus of palliative care is on improving the quality of the person's life. Palliative care is appropriate for anyone facing a serious medical condition, regardless of his or her prognosis, care goals or function...Within the context of palliative care, it is important to note that serious illness and substance use disorders can co-exist, and care of patients with advanced disease and addiction and is beyond the scope of this guideline.
Rhode Island	RI	http://www.health.ri.gov/healthcare/medicine/about/safeopioidprescribing/	2017	http://health.ri.gov/regulations/?parm=Palliative%20care	Palliative care" means patient and family centered medical care that optimizes quality of life anticipating, preventing, and treating suffering caused by advanced serious illness. Palliative care throughout the continuum of illness involves addressing physicial, emtional, social and spiritual needs and facilitating patient autonomy, access to information and choice, Palliative care includes but is not limited to, discussions of the patients goals for treatment, discussion of treatment options appropriate to the patietn, including where appropriate, hospice care; and comprehensive pain and symptom management.
South Carolina	SC	South Carolina Opioid Prescribing Guidelines	2009		

Table Q22-A Summary of State Guidelines for Palliative care

South Dakota	SD	South Dakota Opioid Prescribing Guidelines	2017	Chronic debilitating pain	The Opioid Abuse advisory committee acknowledged that the target population was not individuals with cancer or chronic debilitating pain, or those managing end of life conditions, but rather individuals whose pain management may not require the utilization or duration of drugs that could put a person at risk for addiction
Tennessee	TN	Tennessee Opioid Prescribing Guidelines	2017		
Tennessee	TN	Tennessee Opioid Prescribing Guidelines	2018	Palliative care law pending	Separate adopted legislation for palliative care passed, in regulatory phase
Texas	TX	Texas Opioid Prescribing Guidelines	2015		
Utah	UT	Utah Opioid Prescribing Guidelines	2009	Palliative care exception	The principal focus of these Guidelines is on the use of opioids in the long term treatment of chronic pain, especially chronic, non-cancer pain. These guidelines were not developed to guide treatment of patients with malignant cancer or for patients in hospice or palliative care settings and should not limit treatment for patients for whome pain relief is the primary goal and improved function is not expected.
Vermont	VT	Vermont Opioid Prescribing Guidelines	2016	Palliative care exception	Palliative care means interdisciplinary care given to improve the quality of life of patients and their families facing the problems associated with a serious medical condition. Palliative care through the continuum of illness involves addressing physicial, cognitive emotional, psychological, and spiritual needs and facilitating patient autonomy, access to information, and choice, Defined in 18 V.S.A 2(6). SEE also 9.0 Hospice,Palliative care at the end of life, and end of life care
Vermonth	VT	VT Reference for Physicians on the Use of Opioid Analgesics in the Treatment of Chronic Pain, in the Office Setting	2015	Palliative care exception	As a policy targeting use of opioids for chronic pain, it is not directed at palliative, end of life care.
Virginia	VA	Virginia Opioid Prescribing Guidelines	2017	Palliative care exception	The following situations are exempted from this requirement: The opioid is prescribed to a patient currently receiving hospice or palliative care; the opioid is prescribed to a patient as part of treatment for a surgical or invasice procedure and such prescription is not refillable; the opioid is prescribed to a patient during an inpatient hospital admission or at discharge; the opioid is prescribed to a patient in a nursing home or a patient in an assisted living facility that uses a sole source pharmacy...
Washington	WA	Washington Opioid Prescribing Guidelines	2015	Palliative care referenced	definition incorporated into draft Mar212018. No procedures
Washington DC	WDC	Washington District of Columbia	2013	FSMB Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain (adopted by reference)	Federation of state boards incorporated by reference
West Virginia	WV	West Virginia Opioid Prescribing Guidelines	2016	Palliative care exception	These guidelines provide recommendations for prescribers who are prescribing opioids for pain, including chronic pain lasting longer than three months or past the time of normal tissue healing. Applicable to adult patients that are at least eighteen years old, the guidelines exclude patients prescribed opioids for chronic pain related to active cancer treatment, palliative care, and end of life care
Wisconsin	WI	Wisconsin Opioid Prescribing Guidelines	2016	Palliative care exception	The guidelines excluded patients who are in cancer treatment, palliative care, or end of life care.
Wyoming	WY	Wyoming Opioid Prescribing Guidelines	2016		

Table 5. Care team access to DEA authorized prescribers by specialty

Q5	Do you or the person you are assisting currently have access to a team of physicians who are board certified and registered with DEA to prescribe all your medications including schedule II narcotics? Select all that apply.	Responses						
	Answer Choices	Not available to me		Need, no access (denied, lost,		Available to me when I need it		Total
a	Primary care physician	10.56%	457	17.26%	747	72.17%	3123	4327
b	Pain management physician	13.92%	602	21.41%	926	64.68%	2798	4326
c	Rehabilitation medicine doctor or Physiatrist	33.65%	1230	13.38%	489	52.97%	1936	3655
d	Neurologist	20.55%	791	12.42%	478	67.03%	2580	3849
e	Psychiatrist, Psychologist, Licensed counselor	19.31%	732	9.15%	347	71.54%	2712	3791
f	Orthopedist	24.37%	893	9.33%	342	66.30%	2430	3665
g	Rheumatologist	28.25%	1007	10.55%	376	61.20%	2181	3564
h	Internal medicine specialist	24.20%	868	9.45%	339	66.46%	2380	3587
i	Endocrinologist	32.62%	1108	7.92%	269	67.30%	2020	3397
j	Physical therapist or Occupational therapist	21.10%	793	11.60%	436	67.33%	2529	3758
k	In home care giver support	57.40%	1962	10.42%	356	32.18%	1100	3418
l	COMMENTS: In the last 24 months, have you been denied access to a physician, replaced a physician, or been discharged by physicians who have served as members of your treatment team (please specify the changes you have experienced)?(Please check you state medical records law at this link.http://www.healthinfolaw.org/comparative-analysis/who-owns-medical-records-50-state-comparison) Do you have possession of copies of your health records (medical, insurance filings, lab tests, etc.?)							3885
							Answered (N)	**4616**
							Skipped	0

We're on our own, left to cope however we can

Table 6A. Self-management of pain symptoms post physician release

Q6	If you or the person you are assisting have been discharged by a physician or clinic, please share alternative forms of pain management you are using or have considered using? Select all that apply.	Responses				
	Answer choices	No		Yes		Total
a	I have been discharged from primary care because of my need for pain support and I am concerned about my level of functioning or independence.	60.44%	2272	25.44%	958	3762
b	I have been discharged from pain management care and I am concerned about the current levels of care on my functioning and independence.	54.97%	2048	30.23%	1130	3733
c	I am using over the counter medications (OTCs) to help reduce pain.	30.04%	1164	63.00%	2433	3867
d	The reduction in pain care has increased my use of alcohol or tobacco to control pain levels.	63.63%	2409	31.07%	1177	3788
e	The loss of pain care has resulted in feelings of hoplessness and/or increased my consideration of suicide.	27.97%	1073	62.17%	2394	3848
f	I have borrowed or considered borrowing medications from friends or family to address my pain levels.	67.30%	2584	29.27%	1128	3844
g	I have used or are considered the use of street drugs to address my untreated pain levels.	62.84%	2413	30.43%	1172	3845
h	The discharge from pain care resulted in a decline in my health status.	31.99%	1149	54.60%	1967	3600
i	The discharge from pain care has added extra stress or burden to my daily life	25.77%	939	61.88%	2260	3652
j	My family life is negatively affected by my loss of access to pain care.	23.28%	863	67.77%	2521	3716
k	I have refused some services that I felt were not appropriate for my needs (comments)	53.88%	2006	40.91%	1524	3724
l	I have been told that I must accept services I do not want in order to get services that I need	46.91%	1771	49.46%	1872	3780
m	My refusal of unwanted services resulted in my discharge from primary care, pain management, or other services.	71.21%	2574	21.46%	776	3617
n	Discharge from primary or pain care has resulted in long lapses in the care of my disease(s) and/or pain support	48.41%	1721	42.97%	1531	3561
o	Comments you would like to share (See Table Q6B Patient reported alternatives to opioids for self-management of pain					2925
					Answered (n)	**4145**
					Skipped	489

"My mom was in pain and having an anxiety attack from it after her hip replacement left her with chronic hip pain. My sister took her to the hospital, they sent her out barely paying any mind. She had a heart attack alone at her apartment that night."

"In December 2018, my doctor died after imposing a taper. I consulted one pain management doctor who refused to give me opioids, but instead injected me with steroids against my protests. I experienced a terrible flare up of symptoms with increased pain. So I consulted another pain med doctor who kept seeing me but would not give me any opioids. I saw another primary care doctor who prescribed only one opioid pill per day, against FDA recommendations. He prescribed 3 more black boxed meds that I could

not take without possible death due to interactions. Now I have a new doctor, but he does not take insurance so I have had to mortgage my house to pay for care. He will treat me with opioids but at a half dose. He also uses alternative treatments, which are very expensive and not as effective as opioids but do help my immune system. I have most of my medical records but can't get my last ten years from the doctor who died." (Alabama)

"I was taken off my pain medication and no doctor will pick up my treatment. Doctors keep mentioning DEA. My medication was low dose of Kadian-ER and a breakthrough medication. I am not able to get all of my health records but I am disabled and my judgement list includes Chronic Pain Syndrome. I moved from NV to Michigan. No one wants me as a new patient since I require opioids." (Michigan)

"I was discharged by my Pain Management Physician when the 2016 CDC guidelines were released, without cause. Since then, my Primary Care Physician has refused to treat my pain at all and every Pain Management Physician in my state, Wyoming, and Montana has told me that they are not accepting any new chronic/high impact pain patients that need opioid medications." (Wyoming, Montana)

"I have been denied care from physicians. My primary care physician was severely cutting back on my opioid pain medications and telling me she was taking them away. I had been on opioid pain medications for my chronic pain for over 20 years and they were working. After being told I was to be tapered off of my pain meds I tried another primary care physician and was told he did not prescribe opioids to new patients after agreeing to take me as a client. Since then I have had to fight to get some of my pain meds back but it is not enough (1/3 what I was taking and worked for me). My current primary care doctor, like my past two doctors, is afraid to prescribe opioid pain medications since the CDC changed their recommendations for prolonged opioid use. I am now no longer able to work and lost my job last year as a result of having difficulty doing my desk job. I do have copies of my medical records, insurance filings while I was still insured through my employer, and have copies of my lab tests. I am tired of being treated as a second-class citizen by physicians because of my chronic pain."

"Discharged from several because they said they couldn't help me - didn't have the training or expertise. My issues were too complex. I am generally always under threat of being discharged from pain management and am always under treated for the discomfort I feel associated with my combination of progressive diseases."

Table 11. Opioid prescribing abandonment

Q11	Did you or the person you are assisting have to stop taking any of these medications due to lack of an available physician to prescribe, changes to pharmacy rules, or insurer prohibitions in coverage? Select all that applies.	Responses										
	Answer Choices	YES		NO		NO Physician to Prescribe		Pharmacy will not fill		Insurer will not cover		Cash purchases not accepted		Total
a	Oxycodone (any dose, any form)	28.27%	1133	67.57%	2707	16.48%	660	3.42%	137	4.89%	196	0.87%	35	4006
b	Hydrocodone (any dose, any form)	24.36%	911	71.04%	2657	15.61%	584	2.54%	95	2.65%	99	0.64%	24	3740
c	Morphine (any dose, any form)	13.93%	481	82.31%	2843	9.90%	342	1.59%	55	2.37%	82	0.58%	20	3454
d	Oxymorphone	5.85%	187	90.77%	2900	6.29%	201	1.03%	33	1.16%	37	0.16%	5	3195
e	Methadone	6.77%	220	90.06%	2927	6.65%	216	1.74%	24	1.11%	36	0.31%	10	3250
f	Transdermal fentanyl	10.50%	349	85.68%	2847	9.12%	303	1.38%	46	2.23%	74	0.42%	14	3323
g	Transdermal Buprenorphine or Suboxone (generic or branded)	4.24%	135	92.75%	2956	4.17%	133	0.28%	9	1.57%	50	0.18%	6	3187
h	Ritalin or Adderall	4.29%	137	93.67%	2990	4.10%	131	0.34%	11	0.60%	19	0.28%	9	3192
i	Urine screening required	34.61%	1114	62.57%	2014	4.19%	135	0.31%	10	0.93%	30	0.09%	3	3219
j	What is your state's policy on cash sales for Schedule II medications?													2648
												Answered (N)		**4634**
												Skipped		**0**

Table 12. Contingent substitutions imposed as a condition of prescribing

Q12	Did a change of physician or prescriber result in a change of medications or substitutions of nonopiates, injections, pain pumps, or electrical stimulation devices?	Responses								
	Answer Choices	Gabapentin, Lyrica, Antidepressants or similar		Buprenorphine, Suboxone, Naloxone, or Methadone		Required as a condition of treatment		Various* (describe in comments)		Total
a	Substitution with alternative medications	69.60%	1367	12.63%	248	27.55%	541	26.88%	528	2964
b	Reduction of opiate doses to comply to a guideline or changes to state law	30.27%	567	9.08%	170	47.94%	898	32.73%	613	1873
c	Injections (Epidural steroid (ESI), trigger point, joint)	17.32%	227	3.13%	41	55.99%	734	35.47%	465	1311
d	Pain pump	13.39%	45	5.06%	17	26.19%	88	63.10%	212	336
e	Electrical stimulation device (Spinal cord stimulator or TENS unit, other)	17.22%	161	2.89%	27	40.86%	382	47.27%	442	935
f	Other adjunctive or complementary methods (e.g. pain education, biofeedback, CBT/mindfulness)	25.45%	239	3.73%	35	42.17%	396	40.68%	382	939
g	Surgical recommendations	18.80%	150	2.76%	22	38.97%	311	48.37%	386	798
h	Chiropractic or like therapy	19.13%	146	3.80%	29	34.47%	263	50.98%	389	763
i	Please identify medications, equipment, or alternative protocols (please clarify)									2471
									Answered (N)	2895
									Skipped	1739

"I am a Chronic pain patient experiencing necrosis of the ribs and chest from neutron Radiation Fermi Lab Batavia Illinois. My medications have been reduced to where I am constantly in pain and my quality-of-life is suffering as I am going to become a grandfather and trying to take care of my father that is 88. Trying to push high doses of Suboxone on me but results are not even close. I am trying to work closer with the oncologist to wear maybe he has some answers to deal with my deterioration." (Batavia, IL)

"I was discharged by my pain SPECIALIST just several weeks after he forced *yet another* surgery on me. Every patient in the clinic had meds taken away as of Jan 1st 2019 to comply with the CDC guidelines. My insurance, Medicare and pharmacy are also limiting my pain care to just 10% of what it was. My pain SPECIALIST told me I could "say I'm an addict and go to a methadone clinic." When I replied "no, because you know I'm not an addict and I don't want that on my records", the pain management Dr said "just joking."

"In the fall of 2017 I was discharged from care by my primary physician for reasons not understood by me. I was enduring a forced taper of the opiates I was on for many years & when I asked for them back when the taper was not working, I was discharged. During this time I was also referred to a clinic for cannabinoid treatment which did not work and caused many other intolerable problems & side effects. The doctor refused to grant permission for me to stop this treatment despite my complaints of tachycardia & hypertension & SOB that persisted the entire time I received this treatment. My doctor accused me of drug seeking behavior when all I did was ask for the taper to be reversed as she said she was open to do if I could not tolerate the increased pain levels. A year before all this happened my primary physician was unhappy with me and again she could not say why except that I wasn't responding to treatment & she felt I was too demanding and asking too many questions. I had started looking for another doctor then in the summer of 2016. It took another 3 months to find a physician willing to prescribe my pain medication but I had to agree to try a new intervention of *prolo-therapy* which so far is not working. This agreement was made after my new physician negotiated with the state board. If I did not agree to the new treatment I would not have a doctor or my pain medication at this time. This new treatment is costly in both money & increased pain levels & decreased function."

"My pain specialist would only discuss use of non-opioid medications and spinal cord stimulator. He has put me on gabapentin twice (which makes 4 times total) he does not listen when I report the medications he had me on do not help and cause concerning side effects. He even prescribed the transdermal patches knowing I'm allergic to adhesives."

Table Q6B Patient reported alternatives to opioids for self-management of pain

Group	Patient reported alternative to opioids	f
ACAM	Acupressure	15
ACAM	Acupuncture	320
ACAM	Alexander technique	1
ACAM	Aromatherapy (essential oils)	20
ACAM	Art therapy	2
ACAM	Ayurvedic	6
ACAM	Bikrum Yoga	132
ACAM	Biofeedback	92
ACAM	Chinese medicine	4
ACAM	Cranial Sacral Therapy	5
ACAM	Essential Oils/Terpenes	20
ACAM	Feldenkreis Method	2
ACAM	Magnet therapy	6
ACAM	Magnetic insoles	3
ACAM	Music therapy/ Music (listening)	10
ACAM	Reflexology	6
ACAM	Tai Chi/QiGong	33
ACAM	Yoga	60
Animal-assisted therapy	Service dog, animal rescue, caring for pets	61
Assistive Technology	Wheelchair	43
Counseling	Addiction counseling/ substance abuse counseling	
Counseling	Christian Counseling	7
Counseling	Counseling	26
Counseling	Mental health counseling	20
Counseling	Trager Psychosocial integration	0
Delivery model	Chiropractic	209
Delivery model	Functional Medicine	5
Delivery model	Homeopathy	
Delivery model	Hospice	16
Delivery model	Medical Home	
Delivery model	Naturopathy	2
Delivery model	Occupational therapy	13
Delivery model	Pain Management	1235
Delivery model	Palliative care	43
Delivery model	Primary Care	312
Delivery model	Tenant protocol	4
Electrical stimulation	Deep brain stimulation	
Electrical stimulation	Electrotherapy	
Electrical stimulation	Quell	13
Electrical stimulation	Repetitive transcranial magnetic stimulation (rTMS)	
Electrical stimulation	Rife Machine	1
Electrical stimulation	Scrambler	2
Electrical stimulation	TENS	976
Electrical stimulation	Transcranial magnetic stimulation	2
Electrical stimulation	Transcutaneous electrical stimulation	
Esoteric treatment	Coffee enemas	1
Esoteric treatment	Colon Hydrotherapy	2
Esoteric treatment	Ionic Foot Bathing	2
Esoteric treatment	Prayer and my Faith in God	7
Genotyping	Genetic testing	5
Infusions	Chelation	
Infusions	Infusions (IVIg, Ketamine, Methotrexate)	28
Insurance	Medicare	108
Insurance discontinuance	Insurance coverage discontinuance/ limitations	26
Interventional procedures	Collagen injections	6
Interventional procedures	Dorsal root stimulator	2
Interventional procedures	Epidural injections	182
Interventional procedures	Injections	###
Interventional procedures	Nerve blocks	151
Interventional procedures	Pain pump installation and/or removal	236
Interventional procedures	Prolotherapy	8
Interventional procedures	Radio frequency ablation (RFA)	32
Interventional procedures	Spinal Cord Stimulator SCS	166
Interventional procedures	Spinal Cord Stimulator SCS	166
Interventional procedures	Stem cells	15
Interventional procedures	Trigger Point injections	176
Laser/Light therapy	Cold Laser Therapy	3
Laser/Light therapy	Infrared Treatments	2
Laser/Light therapy	UV Radiation (light) therapy	5
Laser/Light therapy	Monochromatic infrared energy (MIRE)	
Medicaid	State Insurance support	48
Medical Cannabis	Cannabis (marijuana, MMJ)	328
Medical Cannabis	CBD/Cannabis oil	131
Medical device	Eclipse Portable Oxygen Machine	
Medical equipment	Braces	36
Medical equipment	Canes	39
Medical equipment	Cervical traction device	
Medical equipment	Orthotics	4
Medical equipment	Prosthetics/Orthotics	4
Medical equipment	Splints	6
Medical equipment	Walker	22
Medical equipment	Spinal cord stimulator	314
Nutritional supplement	Cancer Diet	
Nutritional supplement	High Dose IV 50g Vitamin C	
Nutritional supplement	Kratom	66
Nutritional supplement	Magnesium	13
Nutritional supplement	Peacure	2
Nutritional supplement	Vitamin B3 injections	
Nutritional supplement	Turmeric/ Curcumin/ ginger/ Bromelain	24
Nutritional supplement	tea	320
Nutritional supplement	Oils	32
Physical/Occupational therapy	Dry needling	31
Physical/Occupational therapy	Float tank	
Physical/Occupational therapy	Heat packs or ice packs	28
Physical/Occupational therapy	Lymphatic Massage	
Physical/Occupational therapy	Massage therapy	375
Physical/Occupational therapy	Myofascial release	
Physical/Occupational therapy	Physical therapy, PT	791
Physical/Occupational therapy	Pilates	3
Physical/Occupational therapy	Pool therapy	11
Physical/Occupational therapy	Rolfing	1
Physical/Occupational therapy	Structural integration	
Physical/Occupational therapy	Water/Aqua therapy	59
Psychoeducation	Cognitive Behavioral Therapy, CBT	9
Psychoeducation	EMDR (Eye Movement Desensitization & Reprocessing)	2
Psychoeducation	Guided Imagery	8
Psychoeducation	Hypnosis	8
Psychoeducation	Meditation	36
Psychoeducation	Mindfulness	64
Psychoeducation	Mirror therapy/Mirror visual feedback	6
Sedative	Ambien	27
Sedative	Vistaril	2
Sedative/hypnotic	Sonata	
Self harm	Suicidal ideation/Suicide	274
Step therapy	Drug substitution/Step therapy	88
Step therapy	Dose Reduction, taper	131
Step therapy	Step therapy	88
Step therapy	Kaiser	27
Substance misuse	Alcohol	126
Surgical procedure	Amputation	
Surgical procedure	Breast reduction/removal surgeries (Mastectomy)	3
Surgical procedure	Extraction	3
Surgical procedure	Spinal Fusions	174
Surgical procedure	Gastric Bypass surgery	
Surgical procedure	Infections debridement	
Surgical procedure	Joint Replacements	4
Surgical procedure	Surgery	698
Tobacco	Tobacco	19
Topical cream	Qutenza	
Treatment discontinuance	Abandoned healthcare	

Table 6C Patient reported drugs and alternatives

Drug Class	Patient reported drug name*	*f*
ACE Inhibitors	Lisinopril	8
Amphetamine	Adderall	9
Amphetamine	VyvanseLisdexamfetamine	16
Analgesic Narcotic	Tramadol	8
Analgesic Narcotic	Ultram	10
Anesthetic	Emla	18
Anesthetic	Ketamine	12
Anesthetic local	Lidocaine	12
Anesthetic topical	TransLidocainePatch	24
Antiadrenergic agents, centrally acting	Clonidine	19
Antibiotic	BiaxinClarithromycin	4
Antibiotic	Clindamycin	5
Antibiotic	Gentamicin	4
Antibiotic	Vancomycin	5
Anticancer Antitumor	Taxol	6
Anticoagulant	ElmironPPS	2
Anticonvulsant	CarbamazepineTegretol	19
Anticonvulsant, Fatty acid	DepakoteDivalproexSodium	24
Anticonvulsant, GABA	GabapentinNeurontin	18
Anticonvulsant, GABA	LyricaPregalbin	31
Anticonvulsant, Hydantoin	Phenytoin	23
Anticonvulsant, Misc	Oxcarbazepine	17
Anticonvulsant, Misc	TopiramateTopamax	9
Anticonvulsant, Triazine	LamotrigineLamictal	15
Antidepressant	BupropionWellbutrin	5
antidepressant SSNRI	DuloxetineCymbalta	15
Antidepressant SSRI	CitalopramCelexa	10
antidepressant SSRI	EscitalopramLLexapro	11
antidepressant SSRI	ParoxetinePaxil	17
Antidepressant, Phenylpiperazine	Trazodone	19
Antidepressant, Tetracyclic	MaprotilineLudiomil	12
Antidepressant, Tetracyclic	MirtazapineRemeron	17
Antidepressant, Tricyclic	Amitriptyline	21
Antidepressant, Tricyclic	AmoxapineAsendin	15
Antidepressant, Tricyclic	Desipramine	11
Antidepressant, Tricyclic	Doxepin	10
Antidepressant, Tricyclic	NortriptylinePamelor	14
Antidepressant, Tricyclic	ProtriptylineVivactil	29
Antidepressant, Tricyclic	TrimipramineSurmontil	11
Antidotes	NaltrexoneVivitrol	10
Antidotes	Narcan	4
Antihistamine	HydroxyzineVistaril	16
Antihistamine	Vistaril	13
Antimanic agent	LithiumCarbonateER	12
Antimigraine agents	Rizatriptan	6
Antipsychotic medication	AripiprazoleAbilify	12
Antipsychotic medication	CariprazineVraylar	3
Antipsychotic medication	ClozapineClozaril	16
Antipsychotic medication	LurasidoneLatuda	5
Antipsychotic medication	OlanzapineZyprexa	16
Antipsychotic medication	QuetiapineSeroquel	0
Antipsychotic medication	RisperidoneRisperdal	17
Antipsychotics	AserapineSaphris	13
Anxiolytic, tranquilizer	BuSpar	5
Anxiolytic, tranquilizer	Buspirone	14
Anxiolytics Sedatives Hypnotics	AmbienZolpidem	20
Anxiolytics Sedatives Hypnotics	SonataZaleplon	17
Benzodiazepine	Alprazolam Xanax	7
Benzodiazepine	AtivanLorazepam	19
Benzodiazepine	XanaxAlprazolam Xanax	19
Benzodiazepine, anti-convulsants	ClonazepamKlonopin	12
Benzodiazepine, anti-convulsants	DiazepamValium	30
Beta Blocker	PropranololInderal	19
Bioflavinoid	Quercetin	18
Botulism toxin	Botox	14
Capsaicin	Qutenza	19
Corticosteroid	Betamethasone	3
Corticosteroid	Cortisone	8
Corticosteroid	DepoMedrolMethylprednisone	20
Corticosteroid	Kenalog	3
Corticosteroid	Methylprednisolone	24
Corticosteroid	MethylprednisoloneAcetateCompounded	13
Corticosteroid	Prednisone	5
Corticosteroid	Triamcinolone	9
Dopaminergic Antiparkinsonism Agents	Mirapex	4
Dopaminergic Antiparkinsonism Agents	Ropinirole	7
Glucose Elevating Agent	Glucose	0
Muscle Relaxers	Baclofen	13
Muscle relaxant	Carisoprodol	8
Muscle relaxant	FlexerilCyclobenzaprine	3
Muscle relaxant	Methocarbamol	24
Muscle relaxant	Soma	17
Muscle relaxant	TizandineZanaflex	12
Narcotic analgesics	Meperidine	16
NSAID	CelebrexCelcoxib	10
NSAID	Diclofenac	16
NSAID	Etodolac	11
NSAID	Indomethacin	16
NSAID	Ketoprofen	12
NSAID	Ketorolac	10
NSAID	Meloxicam	16
NSAID	Nabumetone	13
NSAID	NaproxenAleve	2
NSAID	Toradol	7
NSAID	Voltaren	17
Opioid (C2)	ActiqFentanyl	17
Opioid (C2)	BelbucaBuprenorphine	23
Opioid (C2)	Butrans	12
Opioid (C2)	Codeine	23
Opioid (C2)	DilaudidHydromorphoneExalgo	38
Opioid (C2)	Fentanyl	1
Opioid (C2)	HydrocodoneHysinglaZohydro	32
Opioid (C2)	KadianMorphine	20
Opioid (C2)	Methadone	2
Opioid (C2)	MorphineSulfateER	13
Opioid (C2)	NorcoAcetominophenHydrocodone	18
Opioid (C2)	Nucynta	17
Opioid (C2)	OpanaOxymorphone	15
Opioid (C2)	Oxycodone	17
Opioid (C2)	Oxycontin	16
Opioid (C2)	Percocet	12
Opioid (C2)	Roxicet	13
Opioid (C2)	Roxicodone	6
Opioid (C2)	Vicodin	21
Opioid (C2)	Xtampza	29
Opioid (C2)	Zophydro	22
Opioid (C2)	DuragesicTransdermPtchFentanyl	9
Opioid + agonist	Suboxone	11
Opioid + agonist	Subsys	4
Opioid, Synthetic	BuprenorphineSubutex	21
Opioid/NSAID	EmbedaMorphineNaltrexone	5
Opioid/NSAID	EndocetAcetominOxycodone	9
Opioid/NSAID	LortabAcetominoHydrocodone	2
Sex hormone	Estradiol	16
SNRI	EffexorXRVenlafaxineEffexor	23
Tricyclic Antidepressant	Imipramine	13
Tumor Necrosis Factor Inhibitor TNF	Enbrel	10
Tumor Necrosis Factor Inhibitor TNF	Humira	7

* Drugs associated with suicide as a serious adverse effect (SAE)

Table 2. Completed on behalf of a loved one who is deceased

Q2	I am the family member, of a loved one who is now deceased since the inception of changes to his or her prescribing routine for pain management. (If this question does not apply, skip and go to 3.)	Responses	
	Answer Choices	%	n
a	My loved one's cause of death was of undetermined origin (Y33)	3.20%	14
b	My Loved one took their life due to change to care routine, or withdrawal of medications, or withdrawal of medical management supports for pain (abandonment or forced taper) (Y63.6)	24.43%	107
c	My loved one died accidentally from prescribed medications (any prescription or over the counter) that were substituted for their normal and stable prescribing routine (step therapy or substitution of another class of medications) (Y63).	4.79%	21
d	Other reason (your explanation is voluntary - see comments)	44.75%	196
e	Voluntary comments - please describe factors you believe are important to understand your answer.		328
		Answered (N	**338**
		Skipped	4296

"I have been getting nose bleeds because of how much ibuprofen I have to take. I'm in so much pain, I can't walk, cook for myself or even bathe by myself. I'm in a wheelchair. I've been denied Pain medication on several occasions. I finally found a doctor that would get me Percocet, but they usually treat my disorder with fentanyl patches. Chronic regional pain syndrome is the most painful chronic illness known to modern medicine and rates higher on the McGill pain scale than childbirth, amputation and even cancer. I've applied for disability and got denied because my husband works full time but because of our medical bills we can't afford to live. Today I tried to hang myself, but the rope was too long and I just ended up choking and gaging myself instead. I've also been denied pain medication after I passed out at and ER in front of three nurses and was peeing visible blood and had kidney stones on a scan."

"I am the one now praying that I won't live much longer in this pain. Last time I drove, it took 4 hrs to drive 80 miles and I almost hit two other cars. What can I do miss family functions? Not get food or pay my bills. You have taken everything from me. I sleep sitting up, because it is too painful to lay flat. I want to die"!

Carla Howard's Testimony Prior to her Death

Public Meeting for Patient-Focused Drug Development on Chronic Pain United States Food and Drug Administration (held Monday, July 9, 2018) Consumer (Patients/Care Partners) Feedback - Data collection is continuing

#1

COMPLETE

Collector:	Web Link 1 (Web Link)
Started:	Thursday, February 14, 2019 2:22:21 AM
Last Modified:	Thursday, February 14, 2019 4:14:59 AM
Time Spent:	01:52:38
IP Address:	107.3.255.77

Page 1: This survey is OPEN and accepting submissions.

Q1 My role is (select your primary role)-

Person with chronic pain ,

Comments:

Patient dealing with Chronic Pain for over 38 years due to a near fatal car accident in 1980 that broke me apart from head to toe. Due to the lack of proper testing and limited technology at this time many injuries sustained went undiagnosed, especially in regards to fractures throughout my spine, including many in my neck. I have had 51 ORTHOPEDIC Surgeries and have sought out so many therapies and PT that included CHIROPRACTIC treatment, massage therapy and so many more I finally found an amazing Neurosurgeon who performed the last surgery on my neck and it broke apart in 6 weeks. It took him 6 hours to take this apart and literally glue my neck back together. After the surgery, he told me that my MRI of my entire showed so much damaged that my spine has deteriorated so badly at every Stage and would never support any hardware to repair the damage, he stated that my condition was like bone cancer without the death sentence and that they could at least keep me comfortable with oral meds. That has now been taken away after 12 + years of successful pain management. I also have Inersticial Cystitis, Padgett's Disease, DDD, Osteoporosis and several more Incurable Diseases that ravage my body. My life is now spent in bed 24/7. I currently need 5 more ORTHOPEDIC SURGERIES, but have postponed them all since I had my hip replacement in October of 2018, because just 6 hours after I was released from the hospital after a 2 day stay because my pain was not managed, I went into Cardiac Arrest for the 3rd time. In the ambulance I had a fever of 105.7 and when testing was done, there were no clots or any other issue, I was just suffering with chronic unmanaged pain. I was sent home with a life vest and am awaiting the installation of a defibrillator. This is my life and it is not worth living. An animal would have been put down with the pain I endure.

Public Meeting for Patient-Focused Drug Development on Chronic Pain United States Food and Drug Administration (held Monday, July 9, 2018) Consumer (Patients/Care Partners) Feedback - Data collection is continuing

Q2 I am the family member, of a loved one who is now deceased since the inception of changes to his or her prescribing routine for pain management. (If this question does not apply, skip and go to 3.)	**Respondent skipped this question**
Q3 Do you or the person you are assisting have one or more medical conditions that require you to take medications (schedule II-controlled substances or schedule III-uncontrolled substances) or over the counter drugs? For each, list the symptoms that cause you the most concern.	**YES,** List the multiple co-occurring condition(s) for which you need medications and require pain management support (e.g. diabetes and peripheral neuropathy): DDD, Inersticial Cystitis, Padgetts Disease, Fibromyalgia, Osteoporosis, I currently need Many Orthopaedic Surgeries to replace my other hip, Tears on both knees of my ACL'S, Total reconstructive surgery of both feet and my right hand, heart disease And many more.
Q4 Characterize your disease and pain symptoms in terms of the length of time that you have been dealing with it. Select the answer that best applies to you.	**More than 90 days (chronic/intractable and always present)** , Identify the year you began to receive treatment for chronic or intractable pain associated with your health condition(s) or the point that it began to interrupt your activities of daily living.: 1980 was when I was in a car accident that left me with over 12 broken bones including my Jaw, neck, hip, both arms and collar bones, multiple fractures throughout my entire body and spine, both legs broken in several places, a compound fracture of my Femur. I have Inersticial Cystitis, Padgett's Disease, a heart condition, Osteoporosis, DDD throughout my entire spine.

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Q5 Do you or the person you are assisting currently have access to a team of physicians who are board certified and registered with DEA to prescribe all your medications including schedule II narcotics? Select all that apply.

Primary care physician	**Available to me when I need it**
Pain management physician	**Available to me when I need it**
Rehabilitation medicine doctor or Physiatrist	**Not available to me**
Neurologist	**Not available to me**
Psychiatrist, Psychologist, Licensed counselor	**Not available to me**
Orthopedist	**Available to me when I need it**
Rheumatologist	**Not available to me**
Internal medicine specialist	**Not available to me**
Endocrinologist	**Not available to me**
Physical therapist or Occupational therapist	**Available to me when I need it**
In home care giver support	**Not available to me**
In the last 24 months, have you been denied access to a physician, replaced a physician, or been discharged by physicians who have served as members of your treatment team (please specify the changes you have experienced)?(Please check you state medical records law at this link.http://www.healthinfolaw.org/comparative-analysis/who-owns-medical-records-50-state-comparison) Do you have possession of copies of your health records (medical, insurance filings, lab tests, etc.?):	Yes, I was in pain management for 10 years at the same pain Specialist, but they were bought by another Doctor and after 2 years I was force tapered off my medication down to 85 % less meds than ever since 15 years prior. I left that clinic and my PCP found another Pain Specialist. However, he further tapered my meds to make me compliant to the CDC GUIDELINES. He is currently insisting I have a pain pump installed. I am reluctant, because it is a very expensive procedure. The cost is $40,000 to install plus other fees that will be charged. The cost to fill the pump will be $2,000.00 per month.This will mean that every year, I will have to pay $5,000.00 in my deductible. I do not have that kind of money, but if I don't agree, they will never raise my meds to a level higher than the 90 mme stated in the CDC GUIDELINES. Therfore, I am stuck and will suffer needlessly forever.

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Q6 If you or the person you are assisting have been discharged by a physician or clinic, please share alternative forms of pain management you are using or have considered using? Select all that apply.

I have been discharged from primary care because of my need for pain support and I am concerned about my level of functioning or independence.	**See my comments**
I have been discharged from pain management care and I am concerned about the current levels of care on my functioning and independence.	**See my comments**
I am using over the counter medications (OTCs) to help reduce pain.	**Yes**
The reduction in pain care has increased my use of alcohol or tobacco to control pain levels.	**No**
The loss of pain care has resulted in feelings of hoplessness and/or increased my consideration of suicide.	**See my comments**
I have borrowed or considered borrowing medications from friends or family to address my pain levels.	**No**
I have used or are considered the use of street drugs to address my untreated pain levels.	**No**
The discharge from pain care resulted in a decline in my health status.	**See my comments**
The discharge from pain care has added extra stress or burden to my daily life	**See my comments**
My family life is negatively affected by my loss of access to pain care.	**Yes**
I have refused some services that I felt were not appropriate for my needs (comments)	**See my comments**
I have been told that I must accept services I do not want in order to get services that I need	**See my comments**
My refusal of unwanted services resulted in my discharge from primary care, pain management, or other services.	**See my comments**
Discharge from primary or pain care has resulted in long lapses in the care of my disease(s) and/or pain support	**See my comments**

Comments you would like to share

Our Doctors are afraid of losing their licenses and due to that, in my State of TENNESSEE, no doctor I have seen will give me the help I need, and was stable until 07-2017, when the tapering of my meds were made lower over the course of 5 months. This has greatly contributed to the steady decline of my entire life and I fear i will never again be the same person I was my entire life.

Q7 Describe your pharmacy relationships

My insurance plan 'locks' me into the use of a specific or a single pharmacy for my medications.	**Yes**
My pharmacy treats me like a valued customer.	**No**
My pharmacy has your prescriptions in stock when you present your script?	**No**
My pharmacy provides adequate counseling from my pharmacist when I fill my scripts	**No**
My pharmacist teaches me about common drug interactions (drug-drug; drug-food, drug-OTCs; drug-alcohol)	**No**
If my pharmacy is out of medications, they help ,e locate a pharmacy that can fill my prescription?	**No**
Is your pharmacy a preferred provider to your insurance plan?	**No**
My pharmacist understands my medical needs and history.	**No**
My pharmacy consistently fills my prescriptions.	**No**
My pharmacy has a drug 'take back program' and allows me to return unused medications.	**Yes**
My pharmacy offers medications in packaging appropriate for my use.	**Yes**
Identify the pharmacy(ies) that refuse to fill your prescriptions.:	In January of 2019, my Pharmacy stated that they would fill my Script 1 time and then I would have to go elsewhere after that. My Insurance refused to fill my meds due to the changes in their formulary of my meds. I was placed on another medication they would pay for. My Pain Specialist complied, but would yet again lower the dose considered equivalent and only prescribed the least amount milligram possible, even when my Insurance was willing to pay for and cover a dose 3 times more that my insurance would agree to cover. This only led to an even greater challage to my hearths decline and he refuses to prescribe anything higher. As stated before, they are pushing an expensive, unapproved FDA device that has much evidence of health risks. I cannot afford this, so I have no other recourse but to suffer.

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Q8 What does your pharmacy require from you ? Select all that apply.	**My pharmacy does not meet all of my needs (see comments)** , Describe your pharmacy experience.: Horrible. Walgreens bought our local Pharmacy in 12-2018. In January 2019, my issues with them resulted in my suffering 5 days with no medication and is refusing to fill pain meds for me.
Q9 Have you or the person you are assisting changed your pharmacy one or more times in the last 24 months? Select all that apply.	**I have changed my pharmacy for other reasons** , Explain why you have changed your pharmacy(ies) in the last 24 months.: My pharmacy of 15 years sold to Walgreens in 12-2018.

Q10 Do you or the person you are assisting currently receive a prescription for any of these medications?

Oxycodone (any dose, form)	**NO**
Hydrocodone (any dose, any form)	**YES**
Morphine (any dose, form)	**YES**
Oxymorphone	**NO**
Any other form of opiate (dilaudid, Zohydro, other)	**NO**
Methadone	**NO**
Transdermal fentanyl	**NO**
Transdermal or sublingual Buprenorphine or Suboxone (generic or other)	**NO**
Ritalin or Adderall	**NO**
Urine toxicology screening required	**YES**

Comment
My husband is also disabled and has been since 2009 after an accident at work which damaged his spine and had to have a disc replacement. He only regained a 21% recovery and this was after a Private State Workers Compensation Evaluation.

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Q11 Did you or the person you are assisting have to stop taking any of these medications due to lack of an available physician to prescribe, changes to pharmacy rules, or insurer prohibitions in coverage? Select all that applies.

Oxycodone (any dose, any form)	**YES, NO**
Hydrocodone (any dose, any form)	**YES**
Morphine (any dose, any form)	**NO**
Oxymorphone	**NO**
Methadone	**NO**
Transdermal fentanyl	**NO**
Transdermal Buprenorphine or Suboxone (generic or branded)	**NO**
Ritalin or Adderall	**NO**
Urine screening required	**YES**
What is your state's policy on cash sales for Schedule II medications?	
I do not know.	

Q12 Did a change of physician or prescriber result in a change of medications or substitutions of nonopiates, injections, pain pumps, or electrical stimulation devices?

Substitution with alternative medications	**Gabapentin, Lyrica, Antidepressants or similar**
Reduction of opiate doses to comply to a guideline or changes to state law	**Various* (describe in comments)**
Injections (Epidural steroid (ESI), trigger point, joint)	**Required as a condition of treatment**
Pain pump	**Various* (describe in comments)**
Electrical stimulation device (Spinal cord stimulator or TENS unit, other)	**Various* (describe in comments)**
Other adjunctive or complementary methods (e.g. pain education, biofeedback, CBT/mindfulness)	**Various* (describe in comments)**
Surgical recommendations	**Various* (describe in comments)**
Chiropractic or like therapy	**Various* (describe in comments)**
Please identify medications, equipment, or alternative protocols (please clarify)	

Injections were required often as a means to receive treatment for pain medication. A pain pump is being forced as the only way to offer further help for the INCREASE of pain management.

Q13 How I access my medications:	**A family member or friend fills the prescription for me** ,
	I am home bound or disabled and cannot present my script to a pharmacy by myself

Q14 Do you or the person you are assisting expect to continue to need these or similar medications as the direct result of your current medical diagnosis for the balance of your life? Select all that apply.

Hydromorphone	**NO**
Hydrocodone	**NO**
Oxycodone	**YES**
Morphine	**NO**
Oxymorphone	**NO**
Other form of opiate (Dilaudid, Zohydro, other)	**NO**
Methadone	**NO**
Transdermal fentanyl	**NO**
Transdermal buprenorphine	**NO**
Ritalin	**NO**
Adderall	**NO**

Comment
I must remain on pain medication to function, though currently no at all receiving adequate pain management.

Q15 Factors that I account for in choosing a course of treatment:

My treating provider is located within a reasonable distance from my residence.

,

My insurance plan covers my care needs.

Q16 Barriers that affect my care (briefly describe):

1. Describe the downsides to your current treatment and affect on your daily life.	**maintain my home, exercise, garden, keep Grandchildren, Teaching Sunday School ,attending Church**
2. Describe the challenges and barriers to accessing care for chronic pain in your community.	**No Doctors in TN, especially in my County willing to treat pain above the CDC GUIDELINES. The fear of losing their licenses outweighs their Desire to treat patients.**
3. What would ideal treatment look like if it were available to you?	**Adequate pain management with proper levels that would help in my participation in PT, swimming, gardening, taking care of my 3 Grandchildren; my greatest source of JOY and keeps me in a good place emotionally. Iattend family events or even holidays wis.**
4. How well does your current regimen actually manage your pain symptoms?	**Not at all.**

Q17 Is there something out there that would constitute an improvement to your treatment regimen? Please describe.	**YES,** Comment: A revision of the CDC GUIDELINES that far too many have adopted as law rather than the GUIDELINES that they are. Stop scaring our Doctor's, change what Phamacies are doing by profiling patients who are filling legitimate Scripts, especially when our medical records are valid and current. Stop CMS from placing restrictions on the medication needed for legitimate medical reasons. Stop punishing patients and treating them like Addict's. Stop hurting people who are suffering needlessly from Incurable chronic Diseases and chronic unmanaged pain conditions due to the misfortune of having a crippled and painful disease or injuries not of their making. Please help all who are suffering and struggling to survive in this Nation
Q18 Are there activities or tools that could help you do that help you to manage your pain levels if they were available or affordable? Please share?	**YES,** Comment: Exercise, massage therapy and many more. However, all are very hard to do because I do not feel well enough to participate in the usual activities I did because my pain is so bad I am bedridden. How do you participate in your life when you can barely take a bath, let alone feel like leaving your home due to unmanaged pain conditions?
Q19 Estimate the amount of household income (out of pocket expense) consumed by pain management and support for health care (Select all that apply. Describe) ?	**51-75% of our household income**
Q20 Select all sources for your household income or the household income available to the person you are assisting.	**Social Security Disability (SSDI)** , Other (please specify): Both me & my husband are disabled.

Q21 Insurance Source. Select all sources and indicate whether you insurer covers your needs (schedule II narcotics, physician services, adjunctive care).

No insurance coverage to report	**My plan covers Schedule III drugs, My plan has physicians, clinics, hospitals appropriate for my needs, My plan covers adjunctive services (home care, OT/PT, chronic care, hospice, alternative methods)**
Private insurance (myself or family member)	**My plan covers Schedule III drugs, My plan has physicians, clinics, hospitals appropriate for my needs, My plan covers adjunctive services (home care, OT/PT, chronic care, hospice, alternative methods)**

Medicaid	**Available to me**
Medicare Part A	**My plan covers Schedule II drugs, My plan covers Schedule III drugs, My plan has physicians, clinics, hospitals appropriate for my needs, My plan covers adjunctive services (home care, OT/PT, chronic care, hospice, alternative methods)**
Medicare Part B	**My plan covers Schedule II drugs, My plan covers Schedule III drugs, My plan has physicians, clinics, hospitals appropriate for my needs, My plan covers adjunctive services (home care, OT/PT, chronic care, hospice, alternative methods)**
Medicare Advantage (C [covers parts B&D)	**My plan covers Schedule II drugs, My plan covers Schedule III drugs, My plan has physicians, clinics, hospitals appropriate for my needs, My plan covers adjunctive services (home care, OT/PT, chronic care, hospice, alternative methods)**
Medicare Part D (Drug coverage)	**Available to me, My plan covers Schedule II drugs, My plan covers Schedule III drugs, My plan has physicians, clinics, hospitals appropriate for my needs, My plan covers adjunctive services (home care, OT/PT, chronic care, hospice, alternative methods)**
Tricare	**Available to me**
VA sponsored health care (VAMC, CBOT, other)	**Available to me**
VA Dependent spouse coverage	**Not available to me**
Workman's Compensation	**Not available to me**
My Insurer requires prior authorization for schedule II narcotics	**Available to me, My plan covers Schedule II drugs, My plan covers Schedule III drugs, My plan has physicians, clinics, hospitals appropriate for my needs, My plan covers adjunctive services (home care, OT/PT, chronic care, hospice, alternative methods)**
My insurer will not provide coverage for schedule II narcotics	**Available to me, My plan covers Schedule II drugs, My plan covers Schedule III drugs, My plan covers adjunctive services (home care, OT/PT, chronic care, hospice, alternative methods)**
I have lost my coverage for these medications as a result of changes to my insurance plan	**Available to me, My plan covers Schedule II drugs, My plan covers Schedule III drugs, My plan has physicians, clinics, hospitals appropriate for my needs, My plan covers adjunctive services (home care, OT/PT, chronic care, hospice, alternative methods)**
Changes to policies or physicians have not been affected my current coverage	**Available to me, My plan covers Schedule II drugs, My plan covers Schedule III drugs, My plan has physicians, clinics, hospitals appropriate for my needs, My plan covers adjunctive services (home care, OT/PT, chronic care, hospice, alternative methods)**

Other comments (please specify)
My pain management Doctor refuses to offer adequate pain management that would help me. Instead, he is insisting I have an expensive and unapproved FDA device installed in my body with many health risks involved that are widely considered as a risk to my health.

Q22 In the last 24 months, my support for pain management has -	**Gotten worse, with changes or disruptions to my care** , What has made your care better, the same, or worse (please specify)?: Nothing, I have only gotten worse and have had 3 episodes of Cardiac Arrest since months after the reduction of my pain management medications.

Q23 Rate your satisfaction with the following supports

Primary care	**Not satisfied**
Pain management	**Not satisfied**
Specialty medical care (neurology, orthopedic, rheumatology, etc.)	**Not satisfied**
Integrated pain supports (counseling, psychiatriatry, mental health)	**Not satisfied**
Pharmacy services	**Not satisfied**
Education about my health management	**Not satisfied**
Addiction services	**Not satisfied**
Palliative or chronic care	**Not satisfied**
Insurance plan	**Not satisfied**
Assistive technology or equipment providers	**Not satisfied**
Hospital, skilled nursing, or emergency room services	**Not satisfied**
Communication between members of my health care team	**Not satisfied**

Q24 Demographics (REQUIRED)

Name (First & Last INITIALS ONLY e.g T.L.):	**Carla Howard**
City/Town:	**MURFREESBORO**
State:	**TN**
ZIP:	**37128**
Country:	**UNITED STATES**
Valid email Address:	**carlaw.howard@comcast.net**

Q25 Which category below includes your age?	**50-59**

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Q26 What is the sex or gender orientation you declare?	**Female,** Do you believe that sex or gender is a factor in the quality of your care?: Yes, definitely.
Q27 Racial or ethnic group with which you identify for census purposes	**Caucasian**
Q28 Highest level of education (Select one).	**High school or GED,** **Some college** , Do you manage your health care independently, or do you rely on a friend or advocate to assist you with your medical interactions? If you rely on a friend or advocate, do your health care providers accept their presence, assistance, or advocacy?: My husband is the only one who is assisting me and also has a disability.
Q29 By selecting YES at this step, I agree to share my information with the survey manager with the understanding that results will be used to represent my information to FDA for their July 9 2018 meeting, and that I may withdraw my authorization at any time by contacting the survey manager. My NAME and personally identifiable information will never be publicly released but my choices will be analyzed for the purpose of understanding the status of persons who currently need support for chronic pain in any form. My authorization expires 12 months from the date I complete this survey and submit my results.	**YES**
Q30 I would like to be contacted to participate in research opportunities regarding my personal experiences regarding the management of pain and/or interaction with pain management services, supports.	**Yes**

Carla Denise Howard of Nashville, Tennessee, died of a heart attack, the fourth in a series of heart attacks exacerbated by chronic pain tapering. Her clinician ignored her need for medication management and administered an involuntary taper in response to changes in Tennessee's pain laws and his fear of law enforcement interference after a large multi-state pain clinic shut down. Carla, whose income was based on disability, could not afford and did not want to install a pain pump due to cost and availability of physician servicing issues. She is sorely missed by her family. Her clinician has not been held to account for unilaterally destabilizing her medical management plan of care.

Section IV. Community Pharmacy, Prescription Support and Polypharmacy

Pharmacists have three important roles in the current community pharmacy system: 1) Consultation and education of the treatment team and the patient; 2) Medication therapy management (MTM) conducted by the insurance plan sponsor as part of the case management process, and 3) filling prescriptions and point of sale (POS) edits.

The Medicare Modernization Act of 2003 required that Medicare Part D insurance plan sponsors provide medication therapy management (MTM) services (MTMS) to selected Part D beneficiaries, with the goals of providing education, improving adherence, or detecting adverse drug events and medication misuse. MTM includes five core elements: medication therapy review, a personal medication record, a medication-related action plan, intervention or referral, and documentation and follow-up. While this approach is believed to be effective for patients with multiple chronic conditions, complex medication therapies, high prescription costs, and multiple prescribers, the evidence for this remains weak. A requirement of the contracted plan sponsor and performed in accordance with case management functions, it can be performed by pharmacists with or without a collaborative practice agreement (CPA). As a delivery strategy, it straddles the pharmacy domains of health care system interventions and community-clinical links:

a) Domain 3: Health Care System Interventions

Health care system interventions are strategies used to improve the delivery and quality of care in community clinical settings. Health system and quality improvement changes, such as using electronic health records (EHRs) and analysis of the effect of MTM interventions on most the outcomes of most concern (ie drug therapy problems, adverse drug events, disease-specific morbidity, disease-specific or all-cause mortality, and harms).

b) Domain 4: Community Programs Linked to Clinical Services

This domain—sometimes called community-clinical links—refers to strategies that connect community programs with health systems to improve chronic disease prevention, care, and management. Because this strategy relies on links between community and clinical settings, activities often overlap Domains 3 and 4. Community-clinical links aim to ensure that people with, or at high risk for, chronic diseases have access to quality community resources and support to prevent, delay, or manage chronic conditions. Strategies can include referrals by clinicians to community supports to improve chronic disease self-management or referrals by community programs to clinical services. These links can also involve community delivery and third-party payment for effective programs, which can reduce barriers and increase adherence to clinician recommendations.

Under 423.153(d), a Part D Requirements for Medication Therapy Management Programs (MTMP), a Part D insurance plan sponsor must have established an MTM program that:

a) Ensures optimum therapeutic outcomes for targeted beneficiaries through improved medication use

a) Reduces the risk of adverse events

b) Is developed in cooperation with licensed and practicing pharmacists and physicians

c) Describes the resources and time required to implement the program if using outside personnel and establishes the fees for pharmacists or others

d) May be furnished by pharmacists or other qualified providers

e) May distinguish between pharmacy services provided in community, ambulatory, institutional (hospital, nursing home) settings

f) Is coordinated with any care management plan established for a targeted individual under a chronic care improvement program (CCIP)

Each Part D Sponsor is required to incorporate a Medication Therapy Management Program (MTMP) into their plans' benefit structure. Annually, sponsors must submit a MTMP description to CMS for review and approval. A CMS-approved MTMP is one of several required elements in the development of Sponsor' bids for the upcoming contract year that addresses:

a) Comprehensive medication review (CMR). This is intended to be an interactive person-to-person or telehealth medication review and consultation conducted in real time between the patient and/or other authorized individual, such as prescriber or caregiver, and the pharmacist or other qualified provider. CMR is designed to improve patients' knowledge of their prescriptions, over-the-counter (OTC) medications, herbal therapies, and dietary supplements; identify and address problems or concerns that patients may have; and empower patients to self- identify and address problems or concerns that patients may have; and empower patients to self-manage their medications and their health conditions.

b) Targeted medication review (TMR). This represents ongoing medication monitoring that may address specific or potential medication-related problems.

c) Medication Action Plan (MAP). A description of the specific action items resulting from the interactive CMR consultation, the beneficiary's responsibilities, and the health care provider activities that may affect the beneficiary's tasks.

d) Personal Medication List (PML) - a reconciled list of all the medicines the beneficiary uses (i.e., active medicines).

Prescription Servicing at Point of Sale

a) Inventory management and control

b) Record keeping and reporting

c) Dispensing

Table 10. Opioid prescribing and filling limits

Q10 Do you or the person you are assisting currently receive a prescription for any of these medications?

	Answer Choices	YES		NO		Generic		Brand Name		Prior Approval Required		Dose or unit count limits		Refill requires personal visit to pharmacy		Insurance coverage		Cash purchase, no insurance		Total
a	Oxycodone (any dose, form)	40.00%	1677	58.57%	2456	26.33%	1104	4.03%	169	13.95%	585	16.48%	691	20.68%	869	24.80%	1040	2.69%	113	4193
b	Hydrocodone (any dose, any form)	30.31%	1201	67.55%	2677	20.87%	827	1.74%	69	9.29%	368	11.86%	470	15.49%	614	18.47%	732	2.32%	92	3963
c	Morphine (any dose, form)	19.78%	750	79.50%	3014	12.56%	476	1.87%	71	7.76%	294	8.31%	315	9.79%	371	12.32%	467	1.48%	56	3791
d	Oxymorphone	2.93%	104	96.70%	3433	2.14%	76	0.31%	11	1.58%	56	1.32%	47	1.66%	59	1.80%	64	23.00%	8	3550
e	Any other form of opiate (dilaudid, Zolydro, other)	20.44%	752	78.58%	2891	10.36%	381	2.83%	104	7.39%	272	8.02%	295	8.24%	303	10.90%	401	1.60%	59	3679
f	Methadone	7.10%	257	92.71%	3358	3.67%	133	0.77%	28	2.79%	101	2.46%	89	3.34%	121	3.64%	132	1.13%	41	3622
g	Transdermal fentanyl	10.90%	397	88.88%	3237	5.38%	196	1.92%	70	4.75%	173	4.81%	175	5.46%	199	6.53%	238	0.96%	35	3642
h	Transdermal or sublingual Buprenorphine or Suboxone (generic or other)	4.97%	178	94.77%	3391	1.56%	59	1.37%	49	2.35%	84	1.62%	58	1.82%	65	2.77%	99	0.56%	20	3578
i	Ritalin or Adderall	9.37%	336	90.29%	3237	5.24%	188	0.64%	23	2.90%	104	2.98%	107	3.63%	130	4.80%	172	0.47%	17	3583
j	Urine toxicology screening required	60.68%	2437	39.22%	1575	0.75%	30	0.12%	5	0.97%	39	1.17%	47	1.69%	68	7.00%	281	1.47%	59	4016
k	Comment																			1663
																			Answered (N)	4634

d) Supervision of dispensing

Filling new prescriptions. As stated in 21 C.F.R. § 1300.04 (d), the term "filling new prescriptions for controlled substances in schedule III, IV, or V" means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if: 1. The pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of [21 U.S.C. § 829(b) and (c)] and [21 C.F.R. §§ 1306.21 and 1306.22] (for purposes of this definition, such a prescription shall be referred to as the “original prescription”); 2. The pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in [paragraph (1) of this definition] (i.e., the same controlled substance as described in [paragraph (1)]); and 3. The practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription The practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

Refilling prescriptions. As stated in 21 C.F.R. § 1300.04(k), the term "refilling prescriptions for controlled substances in schedule III, IV, or V”: 1. Means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of [21 U.S.C. § 829(b) and (c)] and [21 C.F.R. §§ 1306.21 and 1306.22], as appropriate; and 2. Does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

Point of sale edits. As of January 1 2019, Pharmacists are required at point of sale (POS) to contact prescribers to verify the legitimacy and appropriateness of specific prescriptions, document the discussion, and enter codes to override the alerts. This new care coordination edit is among the new opioid-related policies that rolled out in January. Implementation of the 2019 Medicare Part D opioid policies is expected to result in more opioid safety edits and beneficiaries will start to be enrolled in drug management programs, more commonly referred to as a “lock-in.” While pharmacists may be familiar with soft and hard edits, additional attention may need to be paid to the requirements of the new opioid care coordination edit. , There are four new opioid safety edits pharmacists should be aware of:

1. 7-day supply limit for opioid naive patients (hard edit),

2. opioid care coordination edits at 90 morphine milligram equivalent (MME),

3. optional hard edit at 200 MME or more, and

4. concurrent opioid and benzodiazepine use or duplicative long-acting opioid therapy (soft edits).

When encountering the opioid care coordination edits, pharmacists should -

- Inform the Medicare Part D plan sponsor if the patient meets the criteria to be excluded from the requirements—i.e., the patient is a resident of a long-term care facility; is receiving hospice, palliative, or end-of-life care; or is being treated for active cancer-related pain—and enter the appropriate override code.

- Communicate overrides at POS and consult with the patient's prescriber to confirm intent. "The consultation should be consistent with current pharmacy practice to verify the prescription and to validate its clinical appropriateness," the resource says. "This is an opportunity for pharmacists to inform the prescriber of other opioid prescribers or increasing amounts of opioids."

- Document the discussion and submit the appropriate override code. "The documentation may include the date, time, name of prescriber, and brief note that the prescriber confirmed intent, did not confirm intent, provided information on patient exclusion, or could not be reached after 'X' number of attempts."

- In the event an issue "is not resolved at the POS and the prescription cannot be filled as written, distribute a copy of the standardized CMS pharmacy notice Medicare Prescription Drug Coverage and Your Rights to the patient."

CMS does not expect pharmacists to contact prescribers if the pharmacist has recently consulted with the prescriber and has up-to-date clinical information, such as what can be found in a prescription drug monitoring program (PDMP) or other records. Pharmacists should also be aware that plans have flexibility in how they implement certain aspects of each edit and drug management programs. Therefore, as information is disseminated by plans regarding these changes, pharmacists will want to closely review these documents to prepare for January.

Table 7. Pharmacy relationships

Q7	Describe your pharmacy relationships	Responses				
		Yes		No		Total
a	My insurance plan 'locks' me into the use of a specific or a single pharmacy for my medications.	32.18%	1432	61.16%	2722	4452
b	My pharmacy treats me like a valued customer.	71.23%	3229	22.44%	1016	4533
c	My pharmacy has your prescriptions in stock when you present your script?	64.38%	2926	24.33%	1103	4543
d	My pharmacy provides adequate counseling from my pharmacist when I fill my scripts	84.39%	3801	12.16%	549	4507
e	My pharmacist teaches me about common drug interactions (drug-drug; drug-food, drug-OTCs; drug-alcohol)	68.79%	3083	27.54%	1233	4483
f	If my pharmacy is out of medications, they help ,e locate a pharmacy that can fill my prescription?	52.00%	2280	40.80%	1785	4382
g	Is your pharmacy a preferred provider to your insurance plan?	74.64%	3301	19.60%	872	4429
h	My pharmacist understands my medical needs and history.	64.08%	2849	30.12%	1338	4447
i	My pharmacy consistently fills my prescriptions.	81.36%	3660	12.60%	567	4501
j	My pharmacy has a drug 'take back program' and allows me to return unused medications.	48.29%	1999	42.62%	1766	4144
k	My pharmacy offers medications in packaging appropriate for my use.	86.81%	3824	10.59%	465	4406
l	Identify the pharmacy(ies) that refuse to fill your prescriptions.					2319
					Answered (N)	4634
					Skipped	0

The Pharmacist's Corresponding responsibility

Prevention of diversion. Pharmacists have a personal responsibility to protect their practice from becoming an easy target for drug diversion. They need to know of the potential situations where drug diversion can occur, and establish safeguards to prevent drug diversion. he dispensing pharmacist must maintain a constant vigilance against forged or altered prescriptions. The CSA holds the pharmacist responsible for knowingly dispensing a prescription that was not issued in the usual course of professional treatment.

Maintenance of Required Controls. Proper controls can be accomplished by following common sense, sound professional practice, and proper dispensing procedures. In addition, pharmacy staff should have knowledge of these safeguards, as it will help prevent and protect the pharmacy from becoming a source of diversion. A pharmacist should encourage other local pharmacists and physicians to develop a working relationship which will promote teamwork and camaraderie.

Ascertainment of legitimate medical purpose. The core legal standard is that a controlled substance may only be prescribed, administered, or dispensed for a legitimate medical purpose by a physician acting in the usual course of professional practice. This requirement has been construed to mean that the prescription must be "in accordance with a standard of medical practice generally recognized and accepted in the United States." The Federal courts have long recognized that it is not possible to expand on the phrase "legitimate medical purpose in the

usual course of professional practice," in a way that will provide definitive guidelines that address all the varied situations physicians might encounter. There are no specific guidelines concerning what is required to support a conclusion that an accused prescriber acted outside the usual course of professional practice. Rather, the courts must engage in a case- by-case analysis of evidence based on prescriber qualifications, resources, patient characteristics and treatment needs as captured in a plan of care to determine whether a reasonable inference of guilt may be drawn from specific facts.

Persons with multiple chronic or complex chronic conditions may be exempted from medical case management under Part D if they are receiving palliative care or hospice services in any qualified location – hospital, nursing home, clinic, or their own home. Or, they may have pharmacy needs that fall outside established sponsored insurance plan payment guidelines for compensated treatment. This doesn't mean that care is not legitimate or that it is not required. It is important to comprehend that medical purpose is derived from collection of the necessary medical evidence through documentation of due diligence that establishes the necessity for medical treatment. If necessary, a disability utilization review (DUR) is conducted to confirm that patient needs might represent legitimate exceptions to the insurance plan sponsor's policy and practices. Some treatment may well fall outside the compensable limits of the sponsored plan policy compact. This may necessitate reviews, appeals or other arrangements to assist the insured patient to access a payor source. The lack of a payor source does not delegitimize care needs and should not be viewed as falling outside the bounds of legitimate medical purpose or practice. The establishment of a medical purpose for payment is not the same as establishing medical purpose for treatment. Ethical, patient centered care must always be the first consideration when deciding how to provide necessary intervention.

Pharmacy fill problems are frequently reported by patients

"My pharmacy is always out of stock, forcing me to taper over time, threatens to cut me off…I have to drive forever to other pharmacies to find the meds to complete a script…Pharmacists scold me in front of other customers." (Florida)

"I changed because the last pharmacy said they would no longer fill my prescriptions because my doctor was too far away. When I asked how close they needed to be they said in the same county. When I pointed out that my doctor was in the same county they told me he was still too far away." (Tennessee)

"I shouldn't have to go to 10 or more pharmacies trying to fill my meds which subjected me to pharmacists being outright nasty and degrading and rude to me! (Arkansas)

"Last summer Walmart started refusing to my pain meds which is a low dose opioid and my dose has never changed. I had to start using a new pharmacy. Walmart often would not even fill my lodine, which is not controlled. They told me that the DEA is responsible for them making these choices." (W. Virginia)

"CDC, Medicare, Pharmacist are now gatekeepers above and beyond my board certified doctors. My doctors have over ten years of medical history and know each other. They all are excellent doctors who see me in person frequently. My current Pharmacist does NOT know my complete medical history has no right to deny my prescriptions."

Table 8. Pharmacy patient filling requirements

Q8	What does your pharmacy require from you ? Select all that apply.	Responses	
	Answer Choices	%	n
a	Medical records	5.80%	269
b	Original prescription	78.36%	3631
c	You or a designee must present your prescription in person	45.32%	2100
d	A government issued identification	58.16%	2695
e	Proof of insurance coverage	57.12%	2647
f	Non-cash payment source for copays	5.37%	249
g	Requirement to fill ALL PRESCRIPTIONS whether or not they are schedule II narcotics	14.07%	652
h	My pharmacy meets all of my needs	59.50%	2757
i	My pharmacy does not meet all of my needs (see comments)	14.91%	691
j	Describe your pharmacy experience.		2244
		Answered (N)	**4634**
		Skipped	0

Table 9. Have you changed pharmacies in the last 24 months?

Q9	Have you or the person you are assisting changed your pharmacy one or more times in the last 24 months? Select all that apply.	Responses	
	Answer Choices	%	n
a	I have not changed my pharmacy in the last 24 months	63.96%	2964
b	I changed my pharmacy because of changes in insurance plan coverage for my medications	9.73%	451
c	I changed my pharmacy because they stopped stocking my medications	7.21%	334
d	I have changed my pharmacy because they frequently claim to be out of stock	11.33%	525
e	I have changed my pharmacy due to pharmacy filling errors (wrong drugs, shortages)	5.83%	270
f	I have changed my pharmacy for other reasons	17.72%	821
g	I have changed my pharmacy due to drug plan price changes from year to year	2.68%	124
h	I am enrolled in a Part D (Medicare) plan	18.00%	834
i	I am enrolled in a Medicaid covered plan	9.02%	418
j	I am enrolled in a private insurance or employer sponsored health plan	12.69%	588
k	I am enrolled in a VA sponsored pharmacy plan	1.94%	90
l	Explain why you have changed your pharmacy(ies) in the last 24 months.		1461
		Answered (N)	**4634**
		Skipped	0

Table Q12. Extracted Patient Reported Drugs by Drug Class with Associated Serious Adverse Events

Drug Class	Drug Name Group1 Extractions	SAEs Associated with Drug Class/Drug	
ACE Inhibitors	Lisinopril	Angioedema	Hyperkalemia
		Bone Marrow Suppression	Hypotension
		Congestive Heart Failure CHF	Liver Disease
		Hemodialysis	Renal Dysfunction Toxicities
Amphetamine	Adderall	Acute Alcohol Intox	Intracranial Pressure
	Vyvanse Lisdexamfetamine	Adrenal Insuffic	Liver Disease
		Arrhythmias	Obesity
		Biliary Spasm	Paradoxical Reactions
		Closed Angle Glaucoma	Prematurity
		Depression	Renal Dysfunction Toxicities
		Drug Dependence	Renal Liver Disease
		Hypotension	Respiratory Depression
		Hypothyroidism	Seizure Disorders
		Impaired GI Motility	Urinary Retention
		Infectious Diarrhea	
Analgesic Narcotic	Tramadol	Angle Closure Glaucoma	Mania
		Cardiovascular Disease	Renal Liver Disease
		Hyponatremia	Seizure Disorders
		Hypotension	Suicidal Tendency
Analgesic Narcotic	Ultram	Seizure Disorders	Mania
		Renal Liver Disease	Hypertension
		Depression	Renal Disease
		Glaucoma	Weight Loss
		Hyponatremia	Urinary Tract Obstruction
Anesthetic	Emla	Acute Alcohol Intox	Infectious Diarrhea
		Adrenal Insuffic	Intracranial Pressure
		Alcoholism	Liver Disease
		Arrhythmias	Phenylketonuria PKU
		Drug Dependence	Prematurity
		Gastrointestinal Obstruction	Renal Dysfunction Toxicities
		Hypotension	Respiratory Depression
		Hypothyroidism	Seizure Disorders
		Impaired GI Motility	Urinary Retention
Anesthetic	Ketamine	Anemia	Hyperkalemia
		Asthma	Hypertension
		Fluid Retention	Platelet Aggregation Inhibition
		GI Inflammation Toxicity	Rash
		Heart Failure	Renal Dysfunction Toxicities
		Hepatotoxicity	Thrombosis
Anesthetic local	Lidocaine	Cardiac Disease	Hypothyroidism
		Dehydration	Neuroleptic Malignant Syndrome NMS
		Dementia	Neutropenia
		Diarrhea Hyperhidrosis	Renal Dysfunction Toxicities
		Fever	Seizure Disorders
		Hyperprolactinemia Breast Cancer	Sodium Depletion

Table Q12. Extracted Patient Reported Drugs by Drug Class with Associated Serious Adverse Events continued

Drug Class	Drug Name Group1 Extractions	SAEs Associated with Drug Class/Drug	
Anesthetic topical	Transdermal Lidocaine Patch	Cirrhosis	Myasthenia Gravis
		Depression Psychoses	Myopathy
		Diabetes	Ocular Herpes Simplex
		Electrolyteimbalance	Ocular Toxicities
		Fluid Retention	Osteoporosis
		Gastrointestinal Obstruction	Positive TB Test
		Hyperadrenocorticalism	Prematurity
		Hyperlipidemia	Peptic Ulcer Disease (PUD)
		Hypothyroidism	Scleroderma
		Infections	Strongyloidiasis
		Liver Disease	Thromboembolism
		MI	Vaccination
Antiadrenergic agents, centrally acting	Clonidine	Acute Alcohol Intox	Hyperprolactinemia
		Agranulocytosis	Hypotension
		Anticholinergic Effects	Lipid Alterations
		Aspiration	Liver Disease
		Central Nervous System (CNS) Depressi	Neuroleptic Malignant Syndrome NMS
		Dementia	Parkinsonism
		Hepatitis B	Renal Dysfunction Toxicities
		Hyperglycemia	Tardive Dyskinesia
		Hyperglycemia Diabetes	Thromboembolism
			Weight Gain
Antibiotic	Biaxin Clarithromycin	Colitis	Myasthenia Gravis
	Clindamycin	Dehydration	Neuromuscular Blockade
	Gentamicin	GI Inflammation Toxicity	Neutropenia
	Vancomycin	Liver Disease	Ototoxicity
		Liver Renal Disease	Renal Disease
		Long QT	Renal Dysfunction Toxicities
Anticancer Antitumor	Taxol	Anaphylaxis	
		Conduction Disorders	
		Hepatic Dysfunction	
		Infections	
		Myopathy	
		Peripheral Neuropathy	
Anticoagulant	Elmiron Pentosan Polysulfate Sodium	Coagulation	
		Hepatic Dysfunction	
Anticonvulsant	Carbamazepine Tegretol	Angle Closure Glaucoma	Lipid Alterations
		Aspiration	Metabolic Acidosis
		Bone Marrow Depress Blood Dyscrasias	Nephrolithiasis
		Dementia	Neuroleptic Malignant Syndrome NMS
		Hematologic Abnormalities	Oligohidrosis Hyperthermia
		Hemodialysis	Renal Dysfunction Toxicities
		Hyperglycemia Diabetes	Severe Liver Disease
		Hyperprolactinemia	Suicidal Tendency
		Hypotension	Tardive Dyskinesia
			Weight Gain

Table Q12. Extracted Patient Reported Drugs by Drug Class with Associated Serious Adverse Events continued

Drug Class	Drug Name Group1 Extractions	SAEs Associated with Drug Class/Drug	
Anticonvulsant, Fatty acid	Depakote Divalproex Sodium	Cirrhosis	Myasthenia Gravis
		Depression Psychoses	Myopathy
		Diabetes	Ocular Herpes Simplex
		Electrolyteimbalance	Ocular Toxicities
		Fluid Retention	Osteoporosis
		Gastrointestinal Obstruction	Positive TB Test
		Hyperadrenocorticalism	Prematurity
		Hyperlipidemia	Peptic Ulcer Disease (PUD)
		Hypothyroidism	Scleroderma
		Infections	Strongyloidiasis
		Liver Disease	Thromboembolism
		MI	Vaccination
Anticonvulsant, GABA	Gabapentin Neurontin	Acute Alcohol Intox	Impaired GI Motility
	Lyrica Pregalbin	Adrenal Insuffic	Infectious Diarrhea
		Alcoholism	Intracranial Pressure
		Anticholinergic Effects	Ischemic Heart Disease
		Arrhythmias	Liver Disease
		Asthma COPD	Myasthenia Gravis
		Biliary Spasm	Myocardial Infarction
		Bradyarrhythmia AV block	Neutropenia
		Cardiogenic Shock Hypotension	Phenylketonuria PKU
		Cardiovascular Disease	Pheochromocytoma
		Cerebrovascular Insufficiency	Prematurity
		Congestive Heart Failure CHF	Prinzmetal Variant Angina
		Cardiovascular Disease (CVD)	Psoriasis
		Depression	Renal Dysfunction Toxicities
		Diabetes	Renal Liver Disease
		Drug Dependence	Respiratory Depression
		Glaucoma	Schizophrenia Bipolar Disorder
		Hyperlipidemia	Seizure Disorders
		Hypersensitivity	Suicidal Tendency
		Hyperthyroidism	Tachycardia
		Hyperthyroidism PKs	Tardive Dyskinesia
		Hypotension	Urinary Retention
		Hypothyroidism	
Anticonvulsant, Hydantoin	Phenytoin	Cirrhosis	MI
		Depression Psychoses	Myasthenia Gravis
		Diabetes	Myopathy
		Electrolyteimbalance	Ocular Herpes Simplex
		Fluid Retention	Ocular Toxicities
		Gastrointestinal Obstruction	Osteoporosis
		Hyperadrenocorticalism	Positive TB Test
		Hyperlipidemia	Peptic Ulcer Disease (PUD)
		Hypothyroidism	Scleroderma
		Infections	Strongyloidiasis
		Liver Disease	Thromboembolism
			Vaccination

Table Q12. Extracted Patient Reported Drugs by Drug Class with Associated Serious Adverse Events continued

Drug Class	Drug Name Group1 Extractions	SAEs Associated with Drug Class/Drug	
Anticonvulsant, Misccellaneous	Oxcarbazepine	Acute Abdominal Conditions	Impaired GI Motility
	Topiramate Topamax	Acute Alcohol Intox	Infectious Diarrhea
		Adrenal Insuffic	Intracranial Pressure
		Arrhythmias	Liver Disease
		Biliary Spasm	Prematurity
		Drug Dependence	Renal Dysfunction Toxicities
		Gastrointestinal Obstruction	Respiratory Depression
		Hypotension	Seizure Disorders
		Hypothyroidism	Suicidal Tendency
			Urinary Retention
Anticonvulsant, Triazine	Lamotrigine Lamictal	Arrhythmias	Proarrhythmic Effects
		Blood Dyscrasias	Rash
		Cardiovascular Dysfunction	Renal Dysfunction Toxicities
		Depression	Renal Liver Disease
		Electrolyteimbalance	Seizure Disorders
		Hepatic Dysfunction	Sinus AV Node Dysfunction
		Meningitis	Suicidal Tendency
		Phenylketonuria PKU	
Antidepressant	Bupropion Wellbutrin	Depression	
		Drug Dependence	
		Glaucoma	
		Liver Disease	
		Renal Liver Disease	
Antidepressant SSNRI	Duloxetine Cymbalta	Adrenal Insuffic	Infectious Diarrhea
		Arrhythmias	Intracranial Pressure
		Biliary Spasm	Liver Disease
		Drug Dependence	Prematurity
		Fever	Renal Dysfunction Toxicities
		Hypothyroidism	Respiratory Depression
		Impaired GI Motility	Seizure Disorders
			Urinary Retention
Antidepressant SSRI	Citalopram Celexa	Acute Alcohol Intox	Infectious Diarrhea
	Escitalopram Lexapro	Adrenal Insuffic	Hypothyroidism
	Paroxetine Paxil	Alcoholism	Impaired GI Motility
		Anemia	Intracranial Pressure
		Arrhythmias	Liver Disease
		Asthma	Obesity
		Biliary Spasm	Paradoxical Reactions
		Closed Angle Glaucoma	Phenylketonuria PKU
		Depression	Platelet AggregationInhibition
		Drug Dependence	Prematurity
		Fluid Retention	Rash
		Gastrointestinal Obstruction	Renal Dysfunction Toxicities
		GI Inflammation Toxicity	Renal Liver Disease
		Heart Failure	Respiratory Depression
		Hyperkalemia	Seizure Disorders

Table Q12. Extracted Patient Reported Drugs by Drug Class with Associated Serious Adverse Events continued

Drug Class	Drug Name Group1 Extractions	SAEs Associated with Drug Class/Drug	
Antidepressant SSRI	Citalopram Celexa	Hypertension	Suicidal Tendency
	Escitalopram Lexapro	Hypotension	Thrombosis
	Paroxetine Paxil		Urinary Retention
Antidepressant, Phenylpiperazine	Trazodone	Acute Alcohol Intox	Liver Renal Disease
		Acute Myocardial Infarct	Neutropenia
		Anticholinergic Effects	Pheochromocytoma
		Bipolar Disorder Screening	Renal Liver Disease
		Bone Marrow Suppression	Schizophrenia
		Cardiovascular Disease	Schizophrenia Bipolar Disorder
		Diabetes	Seizure Disorders
		Glaucoma	Tardive Dyskinesia
		Hyper Hypoglycemia	Thyroid Disorders
			Urinary Retention
Antidepressant, Tetracyclic	Maprotiline Ludiomil	Acute Alcohol Intox	Hypotension
	Mirtazapine Remeron	Adrenal Insuffic	Hypothyroidism
		Anemia	Impaired GI Motility
		Arrhythmias	Infectious Diarrhea
		Asthma	Intracranial Pressure
		Biliary Spasm	Liver Disease
		Drug Dependence	Platelet Aggregation Inhibition
		Fluid Retention	Prematurity
		Gastrointestinal Obstruction	Rash
		GI Inflammation Toxicity	Renal Dysfunction Toxicities
		Heart Failure	Respiratory Depression
		Hepatotoxicity	Seizure Disorders
		Hyperkalemia	Thrombosis
		Hypertension	Urinary Retention
Antidepressant, Tricyclic	Amitriptyline	Acute Alcohol Intox	Neuroleptic Malignant Syndrome NMS
	Amoxapine Asendin	Acute Myocardial Infarct	Infectious Diarrhea
	Desipramine	ALT elevations	Intracranial Pressure
	Doxepin	Anticholinergic Effects	Lipid Alterations
	Nortriptyline Pamelor	Arrhythmias	Liver Disease
	Protriptyline Vivactil	Aspiration	Liver Renal Disease
	Trimipramine Surmontil	Biliary Spasm	Mania
		Bipolar Disorder Screening	Myasthenia Gravis
		Bone Marrow Suppression	Neutropenia
		Cardiovascular Disease	Obesity
		Cataracts	Paradoxical Reactions
		Closed Angle Glaucoma	Parkinsonism
		Central Nervous System (CNS) Depressi	Pheochromocytoma
		Dementia	Prematurity
		Depression	Priapism
		Diabetes	Prolonged Hypotension
		Drug Dependence	QT Prolongation
		Glaucoma	Renal Disease
		Hematologic Abnormalities	Renal Dysfunction Toxicities

Table Q12. Extracted Patient Reported Drugs by Drug Class with Associated Serious Adverse Events continued

Drug Class	Drug Name Group1 Extractions	SAEs Associated with Drug Class/Drug	
Antidepressant, Tricyclic	Amitriptyline	Hyperglycemia Diabetes	Renal Liver Disease
	Amoxapine Asendin	Hyper Hypoglycemia	Respiratory Depression
	Desipramine	Hyperlipidemia	Schizophrenia
	Doxepin	Hyperprolactinemia	Schizophrenia Bipolar Disorder
	Nortriptyline Pamelor	Hypertension	Seizure Disorders
	Protriptyline Vivactil	Hyponatremia	Tardive Dyskinesia
	Trimipramine Surmontil	Hypotension	Thyroid Disorders
	`	Hypothyroidism	Urinary Retention
		Impaired GI Motility	Urinary Tract Obstruction
		Increase Systolic Diastolic BP	Weight Gain
Antidotes	Naltrexone Vivitrol	Aspiration	Lipid Alterations
	Narcan	Cardiovascular Dysfunction	Liver Disease
		Dementia	Neuroleptic Malignant Syndrome NMS
		Hematologic Abnormalities	Renal Dysfunction Toxicities
		Hyperglycemia Diabetes	Septic Shock
		Hyperprolactinemia	Tardive Dyskinesia
		Hypotension	Weight Gain
Antihistamine	Hydroxyzine	Acute Alcohol Intox	Hypothyroidism
	Vistaril	Adrenal Insuffic	Impaired GI Motility
		Anemia	Infectious Diarrhea
		Arrhythmias	Intracranial Pressure
		Asthma	Liver Disease
		Biliary Spasm	Platelet Aggregation Inhibition
		Drug Dependence	Porphyria
		Fluid Retention	Prematurity
		GI Inflammation Toxicity	Rash
		Heart Failure	Renal Dysfunction Toxicities
		Hepatotoxicity	Respiratory Depression
		Hyperkalemia	Seizure Disorders
		Hypertension	Thrombosis
		Hypotension	Urinary Retention
Antimanic agent	Lithium Carbonate ER	Acute Alcohol Intox	Paradoxical Reactions
	Rizatriptan	CAD Risk Factors	Phenylketonuria PKU
		Cardiovascular Disease	Prematurity
		Closed Angle Glaucoma	Prolonged Hypotension
		Depression	Renal Dysfunction Toxicities
		Drug Dependence	Renal Liver Disease
		Liver Disease	Respiratory Depression
		Migraines	Seizure Disorders
		Obesity	Upper GI Disease
Antipsychotic medication	Aripiprazole Abilify	Acute Alcohol Intox	Paradoxical Reactions
	Asenapine Saphris	Adrenal Insuffic	Liver Disease
	Cariprazine Vraylar	Angioedema	Neuroleptic Malignant Syndrome NMS
	Clozapine Clozaril	Arrhythmias	Obesity
	Lurasidone Latuda	Aspiration	Peripheral Edema
	Olanzapine Zyprexa	Biliary Spasm	Porphyria

Table Q12. Extracted Patient Reported Drugs by Drug Class with Associated Serious Adverse Events continued

Drug Class	Drug Name Group1 Extractions	SAEs Associated with Drug Class/Drug	
Antipsychotic medication	Aripiprazole Abilify	Closed Angle Glaucoma	PR Interval Prolongation
	Asenapine Saphris	Creatine Kinase Elevations	Prematurity
	Cariprazine Vraylar	Dementia	Prolonged Hypotension
	Clozapine Clozaril	Depression	QT Prolongation
	Lurasidone Latuda	Drug Dependence	Renal Dysfunction Toxicities
	Olanzapine Zyprexa	Gastrointestinal Obstruction	Renal Liver Disease
	Quetiapine Seroquel	Hematologic Abnormalities	Respiratory Depression
	Risperidone Risperdal	Hyperglycemia Diabetes	Seizure Disorders
		Hyperprolactinemia	Seizure Disorders
		Hypotension	Severe Hepatic Impairment
		Hypothyroidism	Suicidal Tendency
		Impaired GI Motility	Tardive Dyskinesia
		Infectious Diarrhea	Thyroid Disorders
		Intracranial Pressure	Upper GI Disease
		Lipid Alterations	Urinary Retention
			Weight Gain
Anxiolytic, tranquilizer	BuSpar	Acute MI	Intracranial Pressure
	Buspirone	Adrenal Insuffic	Liver Disease
		Depression	Prematurity
		Drug Dependence	Renal Dysfunction Toxicities
		Glaucoma	Renal Liver Disease
		Hypotension	Respiratory Depression
		Hypothyroidism	Seizure Disorders
		Impaired GI Motility	Urinary Retention
		Infectious Diarrhea	
Anxiolytics Sedatives Hypnotics	Ambien Zolpidem	Acute Alcohol Intox	Impaired GI Motility
	Sonata Zaleplon	Acute Myocardial Infarct	Infectious Diarrhea
		Adrenal Insuffic	Intracranial Pressure
		Anticholinergic Effects	Liver Disease
		Arrhythmias	Liver Renal Disease
		Biliary Spasm	Neutropenia
		Bipolar Disorder Screening	Pheochromocytoma
		Bone Marrow Suppression	Prematurity
		Cardiovascular Disease	Renal Dysfunction Toxicities
		Depression	Renal Liver Disease
		Diabetes	Respiratory Depression
		Drug Dependence	Schizophrenia
		Fever	Schizophrenia Bipolar Disorder
		Glaucoma	Seizure Disorders
		Hyper Hypoglycemia	Tardive Dyskinesia
		Hypotension	Thyroid Disorders
		Hypothyroidism	Urinary Retention

Table Q12. Extracted Patient Reported Drugs by Drug Class with Associated Serious Adverse Events continued

Drug Class	Drug Name Group1 Extractions	SAEs Associated with Drug Class/Drug	
Benzodiazepine	Alprazolam Xanax	Acute Alcohol Intox	Impaired GI Motility
	Ativan Lorazepam	Adrenal Insuffic	Infectious Diarrhea
	Xanax Alprazolam	Alcohol Intox	Intracranial Pressure
		Alcoholism	Liver Disease
		Arrhythmias	Phenylketonuria PKU
		Autonomic Dysreflexia	Prematurity
		Depression	Psychoses
		Drug Dependence	Renal Dysfunction Toxicities
		Glaucoma	Respiratory Depression
		Hypotension	Seizure Disorders
		Hypothyroidism	Urinary Retention
Benzodiazepine, anti-convulsants	Clonazepam Klonopin	Acute Alcohol Intox	Hypothyroidism
	Diazepam Valium	Adrenal Insuffic	Impaired GI Motility
		Alcoholism	Infectious Diarrhea
		Anemia	Intracranial Pressure
		Arrhythmias	Liver Disease
		Asthma	Meningitis
		Biliary Spasm	Phenylketonuria PKU
		Blood Dyscrasias	Platelet Aggregation Inhibition
		Bradyarrhythmia AV block	Porphyria
		Depression	Prematurity
		Drug Dependence	Rash
		Fluid Retention	Renal Dysfunction Toxicities
		GI Inflammation Toxicity	Renal Liver Disease
		Heart Failure	Respiratory Depression
		Hepatotoxicity	Sedatives Alcohol
		Hyperkalemia	Seizure Disorders
		Hypertension	Suicidal Tendency
		Hypotension	Thrombosis
			Urinary Retention
Beta Blocker	Propranolol Inderal	Acute Alcohol Intox	Liver Renal Disease
		Acute Myocardial Infarct	Neutropenia
		Anticholinergic Effects	Pheochromocytoma
		Bipolar Disorder Screening	Renal Liver Disease
		Bon Marrow Suppression	Schizophrenia
		Cardiovascular Disease	Schizophrenia Bipolar Disorder
		Diabetes	Seizure Disorders
		Glaucoma	Tardive Dyskinesia
		Hyper Hypoglycemia	Thyroid Disorders
			Urinary Retention
Bioflavinoid	Quercetin	Acute Alcohol Intox	Lipid Alterations
		Aspiration	Liver Disease
		Central Nervous System (CNS) Depressi	Neuroleptic Malignant Syndrome NMS
		Dementia	Parkinsonism
		Depression	Priapism
		Hematologic Abnormalities	QT Prolongation
		Hyperglycemia Diabetes	Renal Dysfunction Toxicities
		Hyperprolactinemia	Tardive Dyskinesia
		Hypotension	Weight Gain

Table Q12. Extracted Patient Reported Drugs by Drug Class with Associated Serious Adverse Events continued

Drug Class	Drug Name Group1 Extractions	SAEs Associated with Drug Class/Drug	
Botulism toxin	Botox	Acute MI	Intracranial Pressure
		Adrenal Insuffic	Liver Disease
		Biliary Spasm	Prematurity
		Drug Dependence	Renal Dysfunction Toxicities
		Hypothyroidism	Respiratory Depression
		Impaired GI Motility	Seizure Disorders
		Infectious Diarrhea	Urinary Retention
Capsaicin	Qutenza	Acute Alcohol Intox	Infectious Diarrhea
		Adrenal Insuffic	Intracranial Pressure
		Alcoholism	Liver Disease
		Arrhythmias	Phenylketonuria PKU
		Biliary Spasm	Prematurity
		Drug Dependence	Renal Dysfunction Toxicities
		Gastrointestinal Obstruction	Respiratory Depression
		Hypotension	Seizure Disorders
		Hypothyroidism	Urinary Retention
		Impaired GI Motility	
Corticosteroids	Betamethasone	Acute Abdominal Conditions	Pheochromocytoma
	Cortisone	Acute Alcohol Intox	Mania
	Depo-Medrol Methylprednisone	Acute Myocardial Infarct	Mania Hypomania
	Kenalog	Alcoholism	MI
	Methylprednisolone	ALT elevations	Myasthenia Gravis
	Methylprednisolone Acetate Compou	Angioedema	Myopathy
	Prednisone	Anticholinergic Effects	Neutropenia
	Triamcinolone	Bipolar Disorder Screening	Ocular Herpes Simplex
		Bone Marrow Suppression	Ocular Toxicities
		Cardiovascular Disease	Osteoporosis
		Cirrhosis	Peptic Ulcer Disease (PUD)
		Creatine Kinase Elevations	Peripheral Edema
		Depression	Positive TB Test
		Depression Psychoses	PR Interval Prolongation
		Diabetes	Prematurity
		Drug Dependence	Renal Dysfunction Toxicities
		Dysphagia Respiratory Disorders	Renal Liver Disease
		Electrolyteimbalance	Respiratory Depression
		Fluid Retention	Schizophrenia
		Gastrointestinal Obstruction	Schizophrenia Bipolar Disorder
		Glaucoma	Scleroderma
		HIV CMV	Seizure Disorders
		Hyperadrenocorticalism	Strongyloidiasis
		Hyper Hypoglycemia	Suicidal Tendency
		Hyperlipidemia	Tardive Dyskinesia
		Hypertension	Thrombocytopenia
		Hyponatremia	Thromboembolism
		Hypotension	Thyroid Disorders
		Hypothyroidism	Urea Cycle Disorders
		Infections	Urinary Retention
		Intracranial Pressure	Urinary Tract Infection UTI
		Liver Disease	Urine Ketone Test
		Liver Renal Disease	Vaccination

Table Q12. Extracted Patient Reported Drugs by Drug Class with Associated Serious Adverse Events continued

Drug Class	Drug Name Group1 Extractions	SAEs Associated with Drug Class/Drug	
NSAID	Celebrex Celcoxib	Depression	Prematurity
	Diclofenac	Drug Dependence	Proarrhythmic Effects
	Etodolac	Electrolyteimbalance	QT Prolongation
	Indomethacin	Fluid Retention	Rash
	Ketoprofen	Gastrointestinal Obstruction	Renal Dysfunction Toxicities
	Ketorolac	GI Inflammation Toxicity	Renal Liver Disease
	Meloxicam	Heart Failure	Respiratory Depression
	Nabumetone	Hepatic Dysfunction	Seizure Disorders
liuretic Hormone Secretion	Naproxen Aleve	Hepatotoxicity	SIADH Syndrome of Inappropriate Antidiuretic Hormone Secretion
	Toradol	Hyperkalemia	Sinus AV Node Dysfunction
	Voltaren	Hypertension	Sodium Depletion
		Hyponatremia	Suicidal Tendency
		Hypotension	Thrombosis
		Hypothyroidism	Urinary Retention
		Impaired GI Motility	Weight Loss
Opioid (C2)	Actiq	---	Hypothyroidism
	Belbuca Buprenorphine	---	Impaired GI Motility
	Butrans	Acute Alcohol Intox	Infections
	Codeine	Acute Myocardial Infarct	Infectious Diarrhea
	Dilaudid Hydromorphone Exalgo	Adrenal Insuffic	Intracranial Pressure
	Duragesic Transdermal Patch Fentany	Alcohol Intox	Lipid Alterations
	Fentanyl	Alcoholism	Liver Disease
	Hydrocodone Hysingla Zohydro	ALT elevations	Liver Renal Disease
	Kadian Morphine	Anemia	Mania
	Methadone	Anticholinergic Effects	Megaloblastic Anemia
	Morphine Sulfate ER	Arrhythmias	MI
	Norco Acetominophen Hydrocodone	Aspiration	Myasthenia Gravis
	Nucynta	Asthma	Myopathy
	Opana Oxymorphone	Asthma COPD	Neutropenia
	Oxycodone	Biliary Spasm	Neuroleptic Malignant Syndrome NMS
	Oxycontin	Bipolar Disorder Screening	Ocular Herpes Simplex
	Percocet	Blood Dyscrasias	Ocular Toxicities
	Roxicet	Bone Fractures	Osteomalacia
	Roxicodone	Bone Marrow Depress Blood Dyscrasias	Parkinsonism
	Vicodin	Bone Marrow Suppression	Pheochromocytoma
	Xtampza	Cardiotoxicity	Phenylketonuria PKU
	Zophydro	Cardiovascular Disease	Platelet Aggregation Inhibition
		Cirrhosis	Platelet Function
		CNS Depression	Porphyria
		Coagulation	Positive TB Test
		Dementia	Prematurity
		Depression	Psychoses
		Depression Psychoses	Peptic Ulcer Disease (PUD)
		Diabetes	QT Prolongation
		Dialysis	Rash
		Drug Dependence	Renal Disease
		Electrolyteimbalance	Renal Dysfunction Toxicities
		Fever	Renal Liver Disease
		Fluid Retention	Respiratory Depression
		Fructose Intolerance	Reye Syndrome

Table Q12. Extracted Patient Reported Drugs by Drug Class with Associated Serious Adverse Events continued

Drug Class	Drug Name Group1 Extractions	SAEs Associated with Drug Class/Drug	
Opioid (C2)	Actiq-Zohydro	G6PD deficiency	Schizophrenia
		Gastrointestinal Obstruction	Schizophrenia Bipolar Disorder
		GI Inflammation Toxicity	Scleroderma
		Glaucoma	Seizure Disorders
liuretic Hormone Secretion		Heart Failure	SIADH Syndrome of Inappropriate
			Antidiuretic Hormone Secretion
		Hematologic Abnormalities	Strongyloidiasis
		Hepatotoxicity	Suicidal Tendency
		Hyperadrenocorticalism	Tardive Dyskinesia
		Hyperglycemia	Thromboembolism
		Hyperglycemia Diabetes	Thrombosis
		Hyper Hypoglycemia	Thyroid Disorders
		Hyperkalemia	Urinary Retention
		Hyperlipidemia	Urinary Tract Obstruction
		Hyperprolactinemia	Vaccination
		Hypertension	Weight Gain
		Hypotension	Weight Loss
Opioid + agonist	Suboxone	Anticholinergic Effects	Hyponatremia
	Subsys	Arrhythmias	Hypotension
		Blood Dyscrasias	Liver Disease
		Depression	Psychoses
		Fructose Intolerance	Renal Dysfunction Toxicities
		Hepatotoxicity	Suicidal Tendency
			Thyroid Disorders
Opioid, Synthetic	Buprenorphine Subutex	Liver Disease	Biliary Spasm
		Seizure Disorders	Acute MI
		Drug Dependence	Impaired GI Motility
		Respiratory Depression	Gastrointestinal Obstruction
		Prematurity	Psychoses
		Urinary Retention	Depression
		Renal Dysfunction Toxicities	Angle Closure Glaucoma
		Adrenal Insuffic	Hyperthyroidism
		Infectious Diarrhea	hyperthyroidism PKs
		Intracranial Pressure	Mixed Manic Episode
			Weight Loss
Opioid/NSAID	Embeda Morphine Naltrexone	Cardiovascular Dysfunction	Mania
	Endocet Acetominophen Oxycodone	Depression	Platelet Function
	Lortab Acetominophen Hydrocodone	Hepatic Dysfunction	Renal Dysfunction Toxicities
		Hepatic Renal Dysfunction	Seizure Disorders
liuretic Hormone Secretion		Hyponatremia	SIADH Syndrome of Inappropriate
			Antidiuretic Hormone Secretion
		Impaired GI Motility	Tooth Pain
		Liver Disease	Weight Loss
Sex hormone	Estradiol	Acute Alcohol Intox	Infectious Diarrhea
		Adrenal Insuffic	Intracranial Pressure
		Arrhythmias	Liver Disease
		Biliary Spasm	Prematurity
		Drug Dependence	Renal Dysfunction Toxicities
		Hypotension	Respiratory Depression
		Hypothyroidism	Seizure Disorders
		Impaired GI Motility	Urinary Retention

Table Q12. Extracted Patient Reported Drugs by Drug Class with Associated Serious Adverse Events continued

Drug Class	Drug Name Group1 Extractions	SAEs Associated with Drug Class/Drug	
SNRI	Effexor XR Venlafaxine Effexor	Acute Alcohol Intox	Hypothyroidism
		Adrenal Insuffic	Impaired GI Motility
		Arrhythmias	Infectious Diarrhea
		Asthma COPD	Intracranial Pressure
		Cardiotoxicity	Liver Disease
		Depression	Prematurity
		Drug Dependence	QT Prolongation
		Gastrointestinal Obstruction	Renal Dysfunction Toxicities
		Glaucoma	Renal Liver Disease
		Hepatic Renal Dysfunction	Respiratory Depression
		Hypotension	Seizure Disorders
			Urinary Retention
Tricyclic Antidepressant	Imipramine	Anemia	Hyperkalemia
		Asthma	Hypertension
		CNS Effects	Platelet Aggregation Inhibition
		Fluid Retention	Rash
		GI Inflammation Toxicity	Renal Dysfunction Toxicities
		Heart Failure	Thrombosis
		Hepatotoxicity	
Tumor Necrosis Factor Inhibitor TNF	Enbrel	Alcoholism	Hepatitis B
	Humira	Congestive Heart Failure CHF	Hyper Hypoglycemia
		CNS Effects	Infections
		COPD	Tuberculosis
		Heart Failure	Wageners Granulomatosis
		Hematologic Abnormalities	Weight Gain

Data information source: drugs.com/interactionschecker

Section V. Barriers to Care

- The faulty conflation off serious chronic illness and multi-morbidities across the lifespan with opioid use disorder and addiction models of care.
- Federal policy makers are vulnerable to undue monied influencers.
- State regulators are vulnerable to undue monied influencers.
- Federal agencies have not allocated the proper resources to understanding who is affected by the problem of opioid misuse, overuse, and abuse.
- Beginning with the federal government, and continuing down to the state agencies and private billers, data systems are inadequate in their construction, remain untested, and fall short of the measures necessary to manage these issues.
- USDOJ and DEA have committed over reach in targeting the chronically ill and the physicians who care for them for enforcement activities without understanding the implications.
- Medical schools have not allocated the resources to modifying their curricula to assure that bias is removed from medical education.
- The Federal government has not committed funding to long term planning for medical education and physician training and recruitment for long term care, primary care, aging care, serious chronic illness, pain management and palliative care, rehabilitative supports, and more.
- Data tools are insufficient in their design to generate information that adequately represents the present problems of health care.
- Data tools don't distinguish between billing systems data and health record data.
- Forensic approaches don't account for the unique nuances between populations, geographic locations, subspecialty implementation, local resources, and construction of the local health care system.
- Insurers are not held to account for the implementation of CARES Part D criteria for management of serious chronic illness and medical necessity.
- The system of value-added payment incentivizes under care of patients and upcoding of billing documentation which creates an entire system of spoiled, untested, unverified data.
- Spoiled data underpins the construction of algorithms within payor tools for Medicare and Medicaid, Workman's compensation, private health insurance.
- Insurance networks are spoiled by DEA encroachment into communities through federal state compacts focused on reduction of opioid dose, days and distribution of illicit and counterfeit medications.
- Spoilage of insurance networks means that physicians, clinics, pharmacies are not available to patients, that patients are continuously having to change their providers, and that this data shows up in the system in a way that harms patients.
- State medical boards, health departments, attorneys general are now servicing federal regulations instead of managing care planning and local services.
- Administrative cost is increasing as patient care is decreasing and even as care cost per unit is increasing.
- Torte reforms have destroyed patient ability to recover from harms imposed by the system of care.
- Medical bankruptcies are at their highest point ever in some states.

- Outcome and impact management is absent from system design.
- Patients cannot obtain the appropriate and necessary continuation of care to manage their complex illnesses.
- The notion of managing care needs through opioid dose dispensing creates a false sense of 'doing something – anything' to address the public health problem of opioid misuse, abuse, and more.
- Clinicians are not being recruited, trained and supported to do the necessary work of serious chronic illness and aging in America.
- There is no transition or warm handoff between service providers across the life span.
- Children with chronic illnesses who transition into adulthood suddenly find themselves thrust into an addiction prevention model as opposed to a serious chronic illness, multimorbidity model.
- Patients are continuously harmed by their encounters with a health care system that is focused on the wrong measures, build to compensate health providers for continuous harms, and yet *nobody is held responsible*.

The Black American Amputation Epidemic

by Lizzie Presser
May 19, 2020

ProPublica is a nonprofit newsroom that investigates abuses of power. Sign up to receive our biggest stories as soon as they're published.

IT WAS A FRIDAY EVENING in the hospital after a particularly grueling week when Dr. Foluso Fakorede, the only cardiologist in Bolivar County, Mississippi, walked into Room 336. Henry Dotstry lay on a cot, his gray curls puffed on a pillow. Fakorede smelled the circumstances — a rancid whiff, like dead mice. He asked a nurse to undress the wound on Dotstry's left foot, then slipped on nitrile gloves to examine the damage. Dotstry's calf had swelled to nearly the size of his thigh. The tops of his toes were dark; his sole was yellow, oozing. Fakorede's gut clenched. *Fuck*, he thought. *It's rotten*.

Fakorede, who'd been asked to consult on the case, peeled off his gloves and read over Dotstry's chart: He was 67, never smoked. His ultrasound results showed that the circulation in his legs was poor. Uncontrolled diabetes, it seemed, had constricted the blood flow to his foot, and without it, the infection would not heal. A surgeon had typed up his recommendation. It began: "Mr. Dotstry has limited options."

Summary and Observations

CDC has specifically requested information about patient and caregiver -

- Experiences managing pain, which might include the benefits, risks, and/or harms of the pain management options listed above.

  See Qs: Q1, Q2, Q3, Q4, Q6, Q10, Q12, Q14, Q20, Q21, Q22, Q26

- Experiences choosing among the pain management options listed above, including considering factors such as each option's accessibility, cost, benefits, and/or risks.

  See Qs: Q2, Q5, Q6, Q7, Q8, Q9, Q11, Q13, Q19, Q23

- Experiences getting information needed to make pain management decisions.

  See Qs: Q1, Q5, Q7, Q8, Q9, Q15, Q16, Q17, Q18, Q23, Q28

The respondents to this survey (nationwide estimated at 19+mil persons with serious intractable pain) are people with serious chronic multi-morbidities who are experiencing conditions for which there is no cure. The majority of them are living with *6 or more* serious conditions, and some of these are known to be rare diseases wherein pain is a major expression of progression of disease processes. A combination of medical modalities and medication management is the appropriate utilization of the healthcare system for these users. Yet regulatory changes, lack of oversight of regulatory outcomes, and over-policing have turned vast numbers of zip codes into medical deserts, leaving patients at great risk of harm in their communities.

Unfortunately, the Federal and state governments have built a system that conflates this population of healthcare users with persons who are addicted or at risk of addiction as the primary feature of their treatment program. So, rather than supporting their health care conditions through an appropriate combination of models and modalities in least restrictive health care settings, patients have been forced into models of acute care focused on reduction of opioid utilization as the primary measured outcome.

People with chronic, intractable illness are marginalized and invisible in the current system

- Incorporation of CDC guidance by the federal government and absorption into state regulations has resulted in uneven changes to state regulations for pain management, palliative care, end of life (hospice) care.
- The difference in care models for serious progressive illnesses, acute pain, perioperative pain, chronic pain, and intractable pain are inadequately incorporated into state regulations and oversight by Boards of Medicine.
- Shifted structures of administrative emphasis on dose dispensing, days of dispensing, and conflating with illegal street supplies has resulted in uneven care through hospital, clinic, and pharmacy closures, creating a loss of capacity to serve people within their home communities and insurance networks.
- Insufficient numbers of trained clinicians are being produced to meet the demand.

- Regulatory over enforcement has not accounted for characteristics of patients or clinical practices and the loss of community capacity imposed by over policing.
- Over policing of the pain care industry through the use of forensic models and error ridden algorithms does not distinguish between levels of service provision and treats all practitioners according to statistical models that are unverified and untested.
- Care access failures are the direct result of failure to plan for the future, inadequate system management by federal agencies, state boards and health policy makers and abdication of responsibility shifted to forensic agencies.
- Insurers are not meeting their obligation to support medical necessity under the CARES Act for chronically ill members with multiple morbidities who require comprehensive integrated supports.
- The failure to account for medical necessity results in harmful encounters, duplicated care and billing costs without outcome tracking.
- Imposition of step therapies as a substitution for opioids is leading to the use of drugs and other modalities of unproven safety and efficacy for which there are no meaningful outcomes tracked.
- Currently, hospital readmission and death are the only two outcomes tracked by Medicare.
- Imposition of services based on acute models of care rather than integrated and palliative care designed to support those with serious illness and multiple comorbidities.
- Insurance coverage is fraught with interruptions and arbitrary implementation of the CMS 2019 rule and the Cares Act Part D Pharmacy program.
- Patient harms are increasing as a result of medical encounters under this system.
- Morbidity and mortality through treatment protocol changes remain unaccounted for as outcome tracking for persons with serious (noncancer) chronic illnesses is absent from system design.

Broken promises

The CDC Guidelines clearly indicated that seasoned patients whose chronic care needs fell into the realm of the palliative care model should be excluded from the application of the Guidelines. Further, CMS adopted the same language of excluding this population for the 2019 final rule implementation. However, both CDC and CMS de-obligated themselves to outcome management leaving this to the states and insurance plans – even after they became aware that both insurers and states had purposefully and erroneously misapplied CDC's recommendations to pain laws through a variety of methods. The harms that have accrued to patients in this period are significant. Every public agency walked away from their obligations. The excess costs that have accrued to the payor system by failing to manage outcomes is simply unacceptable.

Americans expect and deserve more from their government. By breaking their commitment and compact with people who pay for the imposition of these harms out of their pockets, CDC has failed to lead. I hope that you will accept these comments in the spirit of continuous improvement.

I have offered an abbreviated analysis of responses to a national survey conducted over many months. The link to this survey tool is: https://www.surveymonkey.com/r/Y8YXRJ9

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To Whom It May Concern:

I want to thank you for taking public comment on Management of Acute and Chronic Pain. I am a Chronic Intractable Pain Patient. I have an Unspecified Seronegative Autoimmune Polyarthritis. This may be Psoriatic Arthritis and Ankylosing Spondylitis combined, but has not been confirmed. My Rheumatologist and I treat it as such. This falls under Rheumatologic Conditions. The joints that are affected by this are as primary, my spine and pelvis, and secondary my shoulders, knees, ankles, hands, feet and elbows. My initial meeting with my Rheumatologist was in May 2008. This appointment followed 5 years of doctors with big egos telling me that nothing was wrong, I needed to see a psychiatrist, I was a pain pill seeker, etc., etc. That behavior in the medical profession cost me 2 years of treatment, because I could not take one more doctor telling me that it was essentially all in my head and nothing was wrong. These specialists were looking in the wrong places. As they say, when you hear hoof beats, look for horses; I say I am a zebra. Mind you, I started seeking treatment in October 2003. To say the treatment by Spine Specialists and Orthopedic Specialists was demeaning, would be an understatement.

Complications exist in my treatment as is typical with Autoimmune Patients. The treatment protocol (included) is exercise, physical therapy and NSAIDS to start. It is okay to occasionally get steroid injections in problem joints. DMARDS are the next line. TNFi Drugs are next in line. Physical Therapy and regular exercise are a big part of treatment and maintaining flexibility. Oral Steroids can be given during “flares”. Managing stress and weight are part of treatment. NSAIDS caused kidney damage resulting in High Blood Pressure, so I was taken off of them.

DMARDS were not an option because I am allergic to Sulfa based medications. TNFi medications resulted in long bouts with respiratory illnesses, and I was taken off of them. My pain grows worse every year due to the continued damage caused by immune system. This pain is debilitating, depressing and utterly miserable. I currently take an IL-17 Inhibitor. This is nowhere near the effectiveness of the TNFi blockers, but allows some relief from disease progression. Finally, in 2012, I was put on low dose opioids that allowed me to maintain a less than normal existence, but I wasn't in the bed all of the time. I have many responsibilities. I am a wife, mother and an Independent Living Coordinator for the Disabled. I am needed by many people, and I have no plans to let them down. I applied in late 2009 for disability through Social Security, and was approved in early 2011. This disease is disabling due to the level of pain and fatigue.

My Opioid medication started as Tramadol 50 mg, up to 3 times a day in approximately 2012. Around 2014, I went up to Tramadol 50 mg, 4 times per day. Approximately the end of 2014, we added Darvocet to help with nighttime pain. You see, laying down is excruciatingly painful due to disease progression in my spine and pelvis. When Darvocet was removed from the market, I switched to Tylenol 3 at night. It is now 2020 and I take an extended release version of tramadol, ConZip 200 mg and up to 2 Tylenol 3 at night. These medications are a total of 29 MME's, when I need the maximum dose. I enjoy having some flexibility as my pain is worse some days than others. Things that can affect my pain include weather, stress, activity, and injury.

In 2016, my Primary Care Physician informed me that she would no longer assist in my treatment for this disease due to the CDC and P releasing their guidance on opioids. From 2008 until 2016, my PCP and Rheumatologist regularly communicated and worked together to keep my laboratory testing up to date and my medications prescribed. My doctors and pharmacy only change when necessary. I changed pharmacies 1 time when I moved across town, and this year, my PCP will change because she is moving to the Eastern Shore. I agreed to try Pain Management. It took 8 months to get an appointment. The week before my appointment, the receptionist called to tell me that my appointment was cancelled. Most of the doctors had left the practice and they could not take me on as a patient. I went without medication for 6 weeks. My recheck appointment with my Rheumatologist came up. I explained my situation, and he agreed to maintain my medications. He stated that he was willing to take whatever punishment may come, because we had tried other options. The other local Pain Management Clinics wouldn't even see me. I was not a case they were familiar with treating. I have been made to sign a pain contract and be drug tested regularly to make sure that my medication is in my system and that I am not on illicit drugs.

As I now thought everything would be settled with maintaining my medications, my health insurance decided that I now need a Prior Authorization every 6 months instead of every 12 months. This decision again led to 4-6 weeks without my pain medications to allow for the pharmacy, insurance and doctors to get on the same page. This still happens every 6 months. It is frowned upon by all involved if I call in my refill 10 days early to avoid some of the red tape to get sorted out while I still have medications.

Please know that I have been thankful for COVID-19! I haven't had any issues with getting refills. I do hold my breath with every refill to this day because I know that can and will change again. You see, my family history includes both Mother and Father being alcoholics. A psychological profile from testing would make me "High Risk for abuse." I know that my ability to continue being a wife and mother, as well as my ability to serve our participants as an Independent Living Coordinator WILL be affected again soon. I wait with bated breath for the next bomb of this nature the CDC plans to drop on my life. How much longer will I be able to work and maintain a family? A question that no one knows the answer to. By the way, did I mention that stress affects my pain level? My pain level affects my ability to sleep. Lack of sleep and increased pain due to stress make my life as I know it difficult to live. I have now been in counseling every week at a cost of $200 in co-pays per month due to the stress I am under with not knowing when my life will drastically change because of nothing I have done or caused.

Let us look for a minute at what has caused the "Opioid Crisis." "The perfect storm for an Opioid Crisis began with the development and marketing of OxyContin in 1996. This drug was a miracle for those who really needed it. However, the decision was made to market this drug to Primary Care Physicians and to disguise its potency using semantics. By 2001, sales of OxyContin had skyrocketed to $1.1 Billion from $48 Million in 1996, and over 5000 physicians had attended their "Speaker in Training" course held at posh resorts in Florida, Arizona and California. Seeing their success, businesses began setting up "Pill Mills" finding physicians to prescribe the medication with little to no medical treatment. It didn't take long for the word to

get out. The ease of acquiring it, insurance companies sometimes paying most of the cost and addicts lining up to be seen in order to fill the coffers of their dealers made for a crisis never before seen. The FDA was not prepared to handle the situation, and took too long to act resulting in over 200,000 deaths directly linked to this drug. Still, it is impossible to lump everyone in the same basket. Chronic, intractable, non-malignant pain is real and needs to be treated on a case by case basis, by the individual well educated specialist as such.

Also in 1996, states began Medicinal Marijuana legalization. This included California, Oregon, Alaska, Washington, Maine, Hawaii, Nevada, Maryland, Vermont, Montana, Rhode Island, New Mexico, Michigan, New Jersey, Arizona, Delaware and Connecticut. In 2012, Colorado legalized recreational marijuana. 10 more states and Washington DC followed. Decriminalization has occurred in 10 states to date. Since 2012, an additional 25 states have added Medicinal Marijuana programs. While this may be wonderful for the United States of America, across the border in Mexico, drug cartels are losing their cash crop. In November 2012, the Washington Post printed an article showing a predicted loss of revenue of 20%-50% for the cartels. I have included their article with my attached documents. According to the Quartz Daily Brief (also included), methamphetamine seizures between 2012 and 2018 quadrupled. The 2019 National Drug Threat Assessment (attached) shows cartels have increasingly turned to Fentanyl to replace their marijuana losses and increase their revenues. The deaths that are trying to be prevented do not come from legitimate doctors.

Pill Mills were the result of a very greedy business model that was allowed to occur by not having appropriate policies in place. Sure, there are some that write prescriptions for the money,

but the majority write prescriptions for those of us that need the medications. Please allow our Specialists that know and treat our diseases and injuries to continue to treat us without worry of a raid by the DEA! There has to be a better way. Please know that an addict will always find a way to get high. A chronic pain patient that loses their medication can suffer to the point of suicide. Do you really want the loss of these people in your hands?

Sincerely,

Jennifer Beekman

https://qz.com/1449304/when-us-voters-legalize-pot-they-hurt-mexican-cartels/

Legal pot is eating away at Mexican drug cartels' market share.

https://www.washingtonpost.com/news/worldviews/wp/2012/11/09/how-marijuana-legalization-will-affect-mexicos-cartels-in-charts/

From:	Jennifer Beekman
To:	NCIPCBSC (CDC)
Subject:	FW: Public Comment: Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC/NCIPC) - Meeting, July 22, 2020
Date:	Tuesday, July 28, 2020 10:20:16 AM
Attachments:	To Whom It May Concern.docx

From: Jennifer Beekman
Sent: Tuesday, July 28, 2020 10:17 AM
To: NCIPCBS@cdc.gov
Subject: Public Comment: Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC/NCIPC) - Meeting, July 22, 2020

To Whom It May Concern:

I would like to thank you for the opportunity to submit a written public comment. While I may not have experience with permanent injury, I have over a decade of experience as a chronic pain/autoimmune patient. I truly want this board to understand that while emergency medicine is a vital need, there is no room in medicine for cynical and egotistical physicians. I avoid emergency medicine to the extreme due to the generalizations made, condescending tone and lack of accepting that there is no medical text or study that has been done that can compare to the education a chronic pain patient has about their condition. Please believe that when a pain patient shows up at an ER, it is because we have run out of options and are not able to get the pain under control. I would hope that a physician can tell the difference between desperation for treatment and desperation of an addict for medication.

Second, NOTHING ABOUT US WITHOUT US! PLEASE!!! There has to be a cross section of pain patients involved in your workgroup. Pain is very individual. However, there are many commonalities in the disease types and processes. Please add an autoimmune pain patient to your workgroup. I do not know a single autoimmune patient that wants to have the disease they are burdened with. Most of us just want to live our lives as close to normal as we are able to get.

Please see my attached statement that was sent to the CDC during their last public comment period. The opioid crisis is much bigger than any of you admit. There is so much more than just doctors prescribing the opioids that is at play here.

Thank You,
Jennifer Beekman
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My name is Katherine D. Travnicek MD and am writing as a female pain management physician in private practice for 10 years now. I lecture nationally and internationally for various societies on pain management and opioid crisis here in the USA. I use a multidisciplinary approach for acute, sub-acute and chronic pain across various disciplines, utilizing one or more treatment modalities, is when clinically indicated to improve outcomes and function in these patients. These include the following five broad treatment categories, which include the following: 1. non-opioid and opioid medications, 2. restorative therapies (physiotherapy, therapeutic exercise, modalities), 3. behavioral health approaches for psychological, cognitive, emotional, behavioral, social aspects of pain, 4. complementary and integrative (acupuncture, massage, yoga, meditation) as well as 5. ***interventional therapies***. The first set of CDC guidelines were disappointing on two important issues.

First, there were almost ZERO interventional injections noted (only epidurals and joint injections). The guidelines omitted the following: facet joint injections, sacroiliac joint injection, muscle trigger point injections, radio-frequency ablation, neuromodulation such as spinal cord stimulation & dorsal root ganglion stimulation, peripheral nerve stimulation, interspinous spacers (example Vertiflex), and now we have basivertebral nerve ablation. The scientific data (1-5 years) on the efficacy of these procedures is much, much stronger than any medication on the market or other therapies on the market. See details below.

The U.S. Department of Health and Human services (HHS) published final report on Pain Management Best Practices in 2019. ***In that report, interventional procedures are included as one of five integral treatment approaches for comprehensive pain management.*** All primary care healthcare providers closely follow the CDC guidelines or fear them so stopped prescribing opioids completely. This report also states: “Unfortunately, pain specialists are typically not involved in the multidisciplinary approaches of diagnosing and treating a pain patient early enough in his or her treatment, which can lead to suboptimal patient outcomes.” We believe the CDC guidelines can help involve pain specialists earlier in the patient’s treatment process through educating and informing our primary care colleagues (30).

Second, the authors never considered how insurance companies or physicians would respond. If you are not aware, insurance companies are overstepping their bounds and citing CDC guidelines to force patients off of opioids or down to 90 MME. Insurance companies are now denying any opioids unless the patient has cancer pain. Also, many primary care physicians in my home state of Nevada simply stopped prescribing any opioids period due to fear of lawsuits. These absolutely must be addressed.

As you refine and execute the CDC’s pain management principles and educational strategy, ***I strongly request that you prioritize FDA approved and evidence based interventional pain therapies*** for physicians to treat patients suffering from all types of pain. Advancements in medical technologies like spinal cord stimulators, radiofrequency ablation, peripheral nerve stimulation, continuous peripheral nerve block, and interspinous spacers are clinically proven treatment options that have the potential to substantially mitigate or prevent opioid misuse and abuse and reduce undue suffering, disability and debilitating associated with chronic pain. Unfortunately, these promising therapies have been surprisingly absent from previous CDC pain management communications and educational materials.

Therefore, to improve the field of pain management as a whole and to reduce opioid related harms the CDC should implement pain best practices that:

1. Encourage a multidisciplinary approach to pain care, with improved access to and coverage of multidisciplinary treatment options including evidence-based interventional care
2. Treat pain on an individualized basis, without one-size-fits-all rules or policies
3. Develop and disseminate public, patient, and provider education about the full spectrum of pain therapies including interventional techniques, in order to deliver effective, patient-centered care and reduce opioid dependence, tolerance misuse and abuse

Below is a short list of FDA-approved minimally invasive interventional pain techniques that have demonstrated reduction in oral opioid consumption and are sustained solutions:

1. Interspinous process decompression. This device is indicated for lumbar spinal stenosis with symptoms of neurogenic claudication and has been shown to be effective in oral opioid reduction (7).
2. Lumbar facet joint thermal radiofrequency neurotomy (RF neurotomy). Studies suggest that approximately 20-40% of axial low back pain is caused by facet joint arthropathy (8). RF neurotomy is a minimally invasive procedure that can reduce oral opioid consumption by using thermal lesions that ablate the sensory innervation of facet joints (9–13)
3. Spinal cord stimulation therapy (SCS). SCS is a neuromodulation technique with various FDA indications such as post-laminectomy syndrome and has been shown to reduce oral opioid use (14).
4. Intrathecal pump therapy. This intervention has FDA approval for chronic cancer pain. While oral opioids are considered to be a main component of cancer pain management, intrathecal drug delivery allows for overall dose reduction which can not only reduce adverse side effects, but also lead to improved pain control compared to oral administration (15).
5. Peripheral nerve stimulation (PNS). PNS is a reversible neuromodulation technique that stimulates specific peripheral nerves for a variety of chronic pain conditions such as chronic low back, chronic post-amputation stump and phantom limb pain, as well as acute post operative pain following total knee arthroplasty (16–19). PNS has also been shown to reduce opiate consumption in chronic low back pain (LBP) (18,19). LBP is the leading cause of disability in adults in the United States and has a global prevalence of approximately 12% (20–22).
6. Basivertebral nerve radiofrequency ablation. This FDA-approved intervention for vertebrogenic pain recently demonstrated a reduction in the percentage of people using opioids from baseline to 5 years, from 30% to 8% (23). Axial low back is the number one cause of disability in the world and is a challenging condition to manage (24).
To my knowledge, there are no robust studies that demonstrate a decrease in chronic oral opioid consumption after the sole use of other non-pharmacologic treatments such as exercise therapy, cognitive behavioral therapy, or acupuncture. While other non-pharmacologic therapies have a role in chronic pain management, interventional pain procedures have some of the highest quality evidence for pain control and opioid reduction. In addition to the aforementioned procedures, there are a multitude of other interventional pain procedures that have also been shown to improve patient function and quality of life such as vertebral augmentation, epidural steroid injections and intra-articular facet joint injections (25–29).

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From: Kiran Patel
To: NCIPCBSC (CDC)
Subject: CDC Board of Scientific Counselors commentary
Date: Wednesday, July 22, 2020 1:35:34 PM

Hello,

I was not able to give my statement at this afternoons session but wanted my comments to be included. Please see my statement below.

My name is Kiran V. Patel , MD. I am an interventional pain physician practicing in New York City, the Director of Neurosurgical Pain at Lenox Hill Hospital and Pain Medicine fellowship Director at the Zucker Hofstra School of Medicine. As part of this role, I instruct and develop curriculum for physicians who are pursuing careers in Pain Medicine.

I am also a director at large for the North American Neuromodulation Society and member of the American Society of Interventional Pain Physicians.

I appreciate the opportunity to speak in front of the board of scientific counsellors this afternoon. The reality of the opioid epidemic has brought about the cdc opioid guidlelines. However, these guidelines are only one aspect of the solution. As a medical community we need to promote the integration of interventional therapies that can restore patient functionality, in ways that pharmacological treatments cannot.

We as a medical community, must adopt well-researched interventional guidelines to guide the appropriate use of interventional pain procedures as a component of a multidisciplinary approach focused on functional and quality of life measures.

We need governmental guidance to encourage CMS and private payers to provide consistent and timely insurance coverage for evidence-informed interventional procedures early in the course of treatment, before patients are exposed to opioids. CMS and other payers must restore reimbursement to non hospital sites of service to improve access and lower the cost of interventional procedures.

I have seen interventional treatments including spinal cord stimulation, dorsal root ganglion stimulation and peripheral nerve stimulation change patients lives, allowing patients to stop taking opioids and return to a functional life. I urge the counsel to help integrate interventional therapies as the standard of care for the treatment of chronic pain.

Sincerely,

Kiran V. Patel, MD

Sent from my iPhone

From:	Kristi McGarity
To:	NCIPCBSC (CDC)
Subject:	Public comment for 7/22 BSC/NCIPC meeting
Date:	Tuesday, July 28, 2020 6:32:50 AM

To: CDC/BSC/NCIPC staff, Centers for Disease Control, National Center for Injury Prevention and Control
From: Kristin McGarity, Kyle, TX
Re: Public comment for National Center for Injury Prevention and Control (BSC, NCIPC) meeting, July 22

Please accept this written public comment on your July 22 meeting on opioid prescribing.

At your July 22 meeting, Rose Bigham and Anne Fuqua ably covered the plight of patients losing access to opioid medication for painful medical conditions. Dosage thresholds from the 2016 CDC Guideline are NOT intended for insurance payers, state agencies, or law enforcement. Please issue a warning that policies limiting MME should be rescinded now, before this vulnerable population suffers even more harm.

Two comments on CDC presentations:

1) The slide deck from the "Opioid Prescribing Estimates Project" by Christina A. Mikosz contains concerning statements:

"Variation in opioid prescribing practices across clinical indications, even across multiple patients in the same institution." Patients who benefit from high dosage long term, due to genetic mutation or any other reason, end up concentrated with the very few doctors willing to accept such patients. Attempts to standardize dosage and duration inevitably harm them.

"Mismatched with evidence for treatment effectiveness, e.g., chronic pain" means the appropriate research question hasn't been asked. It is not helpful to ask "are opioids effective for chronic pain?" because "chronic pain" includes a huge variety of medical conditions: anything from muscle strains to autoimmune disease to nerve damage to genetic malformation.

The appropriate research question is "can opioids offer benefit to patients with chronic pain who have not achieved sufficient benefit from non-opioid therapies?" This question has, to my knowledge, never been asked.

2) The presentation "CDC Injury Center Updates" by Deb Houry leaves out an important point regarding ACEs (adverse childhood events). ACEs due to parental overdose are well-known, but ACEs can also result from underdose. It is an ACE when a child has to watch a parent slowly deteriorate and lose the ability to work and function, due to inappropriate mandatory taper of opioid medication.

Thank you for your attention to these concerns,

Kristin McGarity, DMA

Kyle, TX
kristi@mcgaritymusic.com

From:	larry aubry
To:	NCIPCBSC (CDC)
Cc:	Hooper, Rebecca
Subject:	FW: Board of Scientific Counselors, National Center for InjuryPrevention and Control, (BSC, NCIPC); Amended Notice of Meeting PreventingOpioid Overdose Deaths Safer and Effective. Opioid workgroup
Date:	Wednesday, July 29, 2020 9:53:28 AM

Amended added AMA statement.

Sent from Mail for Windows 10

From: larry aubry
Sent: Tuesday, July 28, 2020 3:41 PM
To: ncipcbsc@cdc.gov
Subject: Board of Scientific Counselors, National Center for InjuryPrevention and Control, (BSC, NCIPC); Amended Notice of Meeting PreventingOpioid Overdose Deaths Safer and Effective. Opioid workgroup

Board of Scientific Counselors, National Center for Injury Prevention and Control, (BSC, NCIPC); Amended Notice of Meeting

Preventing Opioid Overdose Deaths Safer and effective. Opioid workgroup

NCIPCBSC@cdc.gov

My name is Larry Aubry and my wonderful wife of over 40 years has chronic illnesses without cures that cause her to suffer with intractable pain. The treatments, therapies, medicines and procedures from some of the leading hospitals and physicians in the country were not successful.

For over 20 years she managed her pain with prescription morphine suited to her individual needs. Her benefit and need for effective medication that she has taken safely without harm to others is no different than mine is for different medicines. We benefited as it improved her function and our quality of life. There are 18 million Americans taking long-term prescription opioids and if it didn't work and there was something more effective we would have found and tried it.

The CDC Guidelines marked a turning point to the detriment of the quality of our lives, it has made her life a living hell along with that of other law-abiding citizens who benefit from the long-term use of opioid pain medications in excess of CDC MME guidelines. The harm from the CDC guidelines is not exaggerated or anecdotal, we are living proof and will attest to the harm.

*The CDC guidelines are the catalyst for **widespread and systemic** harm to patients with chronic pain from an illness or injury.*

The widespread and systemic harm includes:

1. Patients being subject to forced or coerced tapering or cut off of opioid pain medications without consent.
    a. Lana Kirby, a retired paralegal and chronic pain patient from Ellenton, Florida,

has collected more than 2,300 survey responses from pain patients about their experiences under the new CDC guidelines. 68 percent said they'd had their doses lowered, and 56 percent had been discharged from a physician's practice.

2. Patient Dehumanization examples such as

    a. Government blame assessment "the raging opioid crisis driven by the nation's more than 50 million chronic pain sufferers."

    b. Katherine Rosenberg -Douglas a reporter for the Chicago Tribune who suffers from chronic pain after breaking her back while roller blading "anyone who requires pain medicine is looked upon as a criminal."

    c. Mary Nissenson, a former TV reporter in Chicago, who established an advocacy group for pain patients called Triumph Over Pain Foundation after a surgery left her suffering from lifelong pain until her death in 2017 stated "pain victims today are treated like rape victims in the '50s. It's like being on trial all the time. "

    d. Patients who have always taken their medications as prescribed say they are treated like drug addicts and are increasingly driven to despair.

    e. "They're questioned in doctors' offices and refused in emergency rooms when they ask for pain relief. Even though they already sign contracts and submit to random drug tests to ensure they're taking their medication as prescribed, politicians have enacted laws that limit the amount of opioids doctors can prescribe, leading to patients' dosages being cut and their pain levels to rise."

3. Patient Discrimination

    a. Health Professionals for Patients in Pain The health-care providers, including three former U.S. drug czars, said the CDC recommendation of a daily numerical threshold for opioid use has led insurers to refuse reimbursement, pharmacies to erect obstacles to obtaining drugs and risks for doctors who want to give out more. "Taken in combination, these actions have led many health care providers to perceive a significant category of vulnerable patients as institutional and professional liabilities to be contained or eliminated, rather than as people needing care," they said in a letter to the agency.

    b. "racist minimization and rationalization of the pain of African American patients in emergency rooms."

    c. "Women, older adults, previously but not currently employed adults, adults living in poverty, adults with public health insurance and rural residents" have a higher prevalence of pain and "socioeconomic status appears to be a common factor" based on indicators that include "education, poverty, and health insurance coverage". Disproportionate impact on the aged, people of color and lower income.

4. Patient Torture

    a. "We have a terrible problem, we have people committing suicide for no other reason than being forced to stop opioids, pain medication, for chronic pain. It's mass hysteria, a witch hunt. It's one of the worst health care crises in our history. There are 5 to 7 million people being tortured on purpose. "— Dr. Thomas Kline, former Harvard Medical School program administrator, and publisher of list of

pain patients who have died by suicide.

b. https://www.youtube.com/watch?v=VfTGWD95uIk

5. Doctors

   a. Dual Loyalty Conflicts-" subordination of the patient's interests, influence the health professional's judgment in ways that are detrimental to the patient's best interest, " a dual-loyalty conflict that has led to a violation of human rights.

      i. When a doctor cuts the dose or discharges the patient, it helps the doctor look good in the eyes of their employer, in the eyes of the regulators, even if the patient dies." "I cannot think of any other situation in healthcare where having your patient die actually makes you look better." "But we are seeing those people kill themselves." Dr. Stefan Kertesz, an addiction medicine specialist at the University of Alabama at Birmingham School of Medicine.

      ii. "Several states and medical boards have turned those guidelines into rigid rules, using the CDC template to enact statutory and regulatory limits that help define what constitutes medical malpractice and criminal wrongdoing"

   b. Persecution of Doctors Prescribe Opioids-

      i. The DEA warns doctors, not the corner drug dealer, might now be the most dangerous peddlers of highly-addictive narcotic prescriptions.

      ii. The number of doctors penalized by the US Drug Enforcement Administration has grown more than fivefold in recent years

      iii. pressure from law enforcement officers concerned about the potential for misuse of prescription drugs resulted in doctors stopping prescribing opioids that relieved their pain.

      iv. Doctors increasingly face charges for patient overdoses and being prosecuted.

6. Medical Boards threaten disciplinary actions for patients who died under their care. So doctors who care for those suffering from pain are the ones who are threatened and charged, should we do the same for psychiatrists who have patients die under their care?

7. Doctors who prescribe opioid pain medications have been characterized as "dirty doctors" who create and sustain addicts, according to law enforcement officials interviewed by CNN.

8. State Legislative Restrictions- 34 have some kind of legislation in place (or in planning stages) with guidelines, limits or other requirements for prescribing opioids. "To date, there is no data on whether and to what extent these laws mediate opioid-related morbidity and mortality".

   a. In an example that typifies the implementation of laws without concern for the Chronic Pain Patients it impacts Ernest Boyd, executive director of the Ohio Pharmacists Association stated "Those patients may be out of luck unless regulations change". "I feel bad for the people in chronic pain because they're going to be the guinea pigs for how we get it back to the middle."

9. Pharmacies have introduced" one-size-fits-all limits on prescriptions, or demand medical information before they'll fill a prescription". Having the corporate entity determine what is — and is not — acceptable clinical practice is deeply troubling."

10. Pharmacists- "physicians and pharmacists fear they could be flagged by the state or the Drug Enforcement Agency for prescribing opiates, said Ernest Boyd, executive director of the Ohio Pharmacists Association."
    a. Pharmacists are denying or changing prescriptions "sometimes with the knowledge of the physician and sometimes not.""
11. Press The media isn't showing — the side of the chronic pain patient,
    a. Doctors have been falsely targeted for this illegal epidemic, pushed by the mainstream media and fake news nationwide.
12. Insurance Companies have reduced or eliminated coverage of opioid medications though it was for a pre-existing condition and/or disability.

The CDC and advocates for the guidelines conclude that "a sharp increase in prescriptions for opioids resulted in a corresponding rise in addiction and overdose deaths". This is a fallacy based on correlation existing prior to 2011. Correlation does not mean causation. Leadership cannot be achieved nor should strategy be set by focus on a rear-view mirror.

This oversimplistic correlation is used to justify a prescribed solution that suits interests of certain stakeholders. It does not take into account that factors besides "biological mechanisms, such as a person's social environment, are also critical in a person's risk for drug use." "An alternative to the gateway-drug hypothesis is that people who are more vulnerable to drug-taking are simply more likely to start with readily available substances such as marijuana, tobacco, or alcohol, and their subsequent social interactions with others who use drugs increases their chances of trying other drugs." Findings indicate the highest association is between marijuana and alcohol use.

Here are the facts (2011-2018):

1. Total Overdose deaths increased from 41,340 to 67,367 for a 62.6% increase.
2. Overall opioid volumes in MMEs have declined by 43%.
3. High-dose prescriptions for 90 MMEs per day or greater declined by 61%.
4. Prescription Opioid Overdose Deaths were within a range of 14,145 to 17,087, an average of 15,342 deaths per year and were 15,140 in 2011 and 14,975 in 2018. This value is actually lower as a single death might be included in more than one category when describing the rate of drug overdose deaths involving specific drugs.

From 2014-2018 Annual opioid prescriptions declined by 31% from 244.5 to 168.9 million.
As of 2018 the Justice Department we had the lowest opioid prescription rates in 18 years.

Please refer to the attached article and see more facts that dispel the fallacy that Prescription Opioids are the cause for increasing overdoes deaths.
https://www.painmanagementnursing.org/article/S1524-9042(19)30072-4/fulltext?fbclid=IwAR1J4taeb_7JNO-5lBSeHsJ4LfHJrazgYQWb_UT1vg6IiB7V716wNJ4spDA

The current approach of minimizing the availability of prescription opioid pain killers is ineffective and harmful to law abiding patients. If a patient does not want to use an opioid pain medication, they can decide that with the doctor without influence or coercion from the CDC or DEA.

Conflating the misuse of opioids with their legitimate medical use, and treating all opioids — illegal or prescription — alike is stigmatizing patients for whom opioid painkillers are necessary and

medically appropriate. This stigmatization and the existence of this guideline has been the catalyst for the torture and death of chronic pain patients.

If the intent of the guidelines is to conduct the largest medical experiment on a human population without informed or with coerced consent, in violation of the Nuremburg Code, it has been a successful violation of human rights. The CDC and advocates for this experiment proceeded with the guidelines and chose not to measure the outcomes nor be concerned with them so it can state any feedback not in alignment with their view is anecdotal or exaggerated.

The CDC needs to correct the harm it has caused and for which it is responsible by withdrawing its guidelines. Withdraw the CDC guidelines, stop the harm to patients and respond by replacing it with the AMA recommendations as follows https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2020-6-16-Letter-to-Dowell-re-Opioid-Rx-Guideline.pdf

Sincerely,

Larry Aubry

From:	Richard Lawhern
To:	NCIPCBSC (CDC); CDC Info (CDC cdcinquiry.onmicrosoft.com)
Subject:	Followup on " Comment on NCIPC Board of Scientific Counselors Meeting July 22, 2020"
Date:	Thursday, July 23, 2020 11:39:40 AM

For the administrators, NCIPC BSC,
Copy Dr Debra Houry

It has come to my attention that some of those who spoke in the July 22 public input session of the Board of Scientific Advisers meeting had not pre-registered to speak. However, I did register via the survey monkey link you provided a month ago and I was not called. Given that this is a violation of the published participation rules, I must suggest that this action creates the appearance of your selectively seeking to silence my voice as an effective and widely read patient advocate and critic of the fatally flawed 2016 CDC Guidelines.

With this background in mind, I hereby formally request that my short address (previously shared with you and copied below) be circulated to all members of the BSC and to the newly selected Opioid Workgroup. I further request that this text be published with the transcribed minutes of this meeting, as an addendum to the public session.

I look forward to your confirmation of these corrections.

Sincerely yours,

Richard A "Red" Lawhern PhD
Alliance for the Treatment of Intractable Pain

ATIP
The Alliance for the Treatment of Intractable Pain™

Twitter: @Lawhern1
Facebook: https://www.facebook.com/red.lawhern
My Publications: http://www.face-facts.org/Lawhern
Personal Website: http://www.lawhern.org

From: Richard Lawhern <lawhern@hotmail.com>
Sent: Wednesday, July 22, 2020 10:40 AM
To: NCIPCBSC@cdc.gov <NCIPCBSC@cdc.gov>; CDCInfo <cdcinfo@cdcinquiry.onmicrosoft.com>
Subject: Comment on NCIPC Board of Scientific Advisers Meeting July 22, 2020

For members of the Board of Scientific Advisors and senior management of the CDC

The following comments have been prepared for your July 22 meeting, and have been published in advance on the blog of Dr Lynn Webster, as follows:

https://www.lynnwebstermd.com/2020/07/04/three-minutes-to-change-the-world/

Your decision to shorten time allowed for public participants to two minutes will likely have forced me to shorten this presentation. However here is the original three-minute address, with minor editing:

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Three Minutes to Change the World

Richard A. Lawhern, PhD
Presentation to the Board of Scientific Counselors
Of the CDC National Center for Injury Prevention and Control
July 22, 2020

Good day. I am Richard A. Lawhern, PhD, a co-founder of the Alliance for the Treatment of Intractable Pain. I am a non-physician patient advocate with 24 years experience in this field and over 90 published articles and papers. I speak on behalf of millions of pain patients who have been profoundly and needlessly damaged by the 2016 CDC Guidelines on prescription of opioids. I have no financial conflicts of interest.

As this body deliberates on revision of the CDC guidelines, you must embrace these facts:

- The US Agency for Healthcare Research and Quality informs us that there are no profiling instruments that accurately predict risks of opioid dependency, tolerance, or addiction in individuals. However, as they fail to inform us, there never will be.

- Genetic polymorphism in P-450 series liver enzymes that metabolize opioids generates a wide natural range of minimum effective dose. Case reports indicate some patients are helped by as little as 20 MMEDD, while others benefit from over 2000 MMEDD — without significant side effects, sometimes for periods of years.

- Over-prescribing did not create our US opioid “crisis.” Dr Nora Volkow, Director of NIDA, tells us “addiction is not a predictable outcome of opioid prescribing.” Risk of addiction to medically managed opioids is less than 1%. Overdose mortality is three to six times higher in youth under age 24 than in seniors over age 62. But prescribing in seniors is three to six times higher than in youth. U.S. states with higher prescribing rates have overdose mortality rates below the national average. These demographic inversions give the lie to the notion that doctors "over-prescribing" to pain patients *ever* contributed significantly to the bogus "opioid epidemic".

- The American Medical Association has repudiated MMED as a measure of risk or benefit, and characterized “high prescriber” letters as a blacklisting of doctors and their patients, violating legal due process. Denial of pain care when it is available constitutes patient abuse and desertion.

It is time to admit publicly that the 2016 CDC guidelines were not only misapplied, but wrong on facts, science, and medical ethics. Contrary to the narratives of fringe element anti-opioid zealots and their insurance company sponsors, medically managed opioid analgesics are safe, effective and indispensable. For millions of pain patients, no effective alternative treatments exist.

Thank you for letting me speak. I can be available by conference call to expand on the points made above to other public or private meetings of the Board of Scientific Advisors. My phone contact is 703.216.0724 0900-1600 Eastern Time weekdays.

Richard A "Red" Lawhern PhD
Twitter: @Lawhern1
Facebook: https://www.facebook.com/red.lawhern
My Publications: http://www.face-facts.org/Lawhern
Personal Website: http://www.lawhern.org

From: lbear12002@yahoo.com
To: NCIPCBSC (CDC); CIAAG.Net; Shasta Harner
Subject: Public Comment 7/22/2020
Date: Wednesday, July 22, 2020 1:47:49 PM

Research shows the CDC knew before hand harm would be the result of of the 2016 Guidelines and chose to proceed. PROP presented this theory to the FDA and was rejected for good reason but then was accepted by the CDC. It is demonstrable the NPS/ " Best Practices" is a study being conducted on pain pts against their will because no one in true pain can bear being removed from meds for long term studies so the only way to acquire studies is to force pts off meds. These entities have a goal of study, experimentation, forced tapers, alt treatments and if all else fails pushing all pain pts on to Suboxone or Buprenorphine or implanting them with a pump or SCS.

This caused a human genocide of senseless, preventable, suffering , death and suicide. What has become treatment of pain in America violates the Nuremberg Code of Ethics, 42 Us Code 1395. and the civil and human rights of all the innocent patients who have been harmed or killed because of this. Since the Guidelines, there has been nothing but a land slide of papers written, theories published, opinions formed all drowning out the very real voices of people in pain crying out for mercy, sanity, reason. compassion, and equity to return to the treatment of pain pts who are treated unlike any other patient that exists.

The AMA has taken a stance that laid out in no uncertain terms what they feel should be done in regard to the Guidelines. In keeping with the AMA , I as a member of Chronic Illness Advocacy & Awareness Group, implore the CDC to immediately withdraw the guidelines and restore care of pain pts to Drs . Now would be the time for the CDC to own what they have done and make that happen,

You own responsibility for the preventable, disabling, suffering, death , suicide. Loss of life, quality of life, jobs, relationships, dreams, goals and that as simple but priceless as being able to perform even basic ADLs in people who were fully functional on pain medication, but were destroyed by your hand and called collateral damage. Do the the right thing. Tell the illicit truth. It is not Rx meds that are causing the drug crisis in this nation. It has been and is illicit drugs and while all the money and power of our government and alphabet agencies are busy scapegoating pain pts, the real killer is still out there and numbers of deaths from illicit drugs and polypharmacy climb while you also , as has been the mode from the start , fail to factor in the shattering role that alcohol plays in this nightmare and until it is addressed head on as a major factor , people will continue to die.

It is abhorrent that treatment for addiction which is now called a disease is prioritized and protected but the disease of pain is treated as a moral failing or character flaw and this is not the first conference I have participated in during which concern for pain pts was not expressed. It is obvious that CDC has no intention of doing what it should do which is track patient outcomes that include staggering numbers of deaths to either medical collapse or suicide and equaling staggering numbers of people who suffer without relent in lives that are not lived but only existed in like some sort of never ending nightmare. I have heard pts express jealousy that they do not have a terminal Dx and have no idea how long they will be trapped in hell. Your priority should be patient outcomes but it is clear your number one goal is to reduce Rxing in quantity, dose, frequency and availability at all costs, literally, even if the cost is human life.

This has caused pts suffering trauma, cancer, burns, chronic issues, pts on hospice are being denied pain care. It is astounding that this has reached the level of extensive, invasive surgical procedures being done with local anesthesia and IV Tylenol or Ibuprofen and no opiates for pain. The American Cancer Society ranks care of women with breast cancer/mastectomies as so poor that it has reached 3rd world status. Pts are being traumatized, harmed and killed outright. Insurance companies now incentivize Dr to do surgery and NOT Rx pain meds. We no longer have a civil society but a barbaric medical system that has been totally destroyed by the 2016 GLs

Lastly why is it you have insisted the 2016 GLs were intended for acute pain guidance for Mds but this morning you said the truth and said it is about chronic pain that you are targeting so you lied. Also why is Dr Chou the only person in this conference who did not acknowledge whether or not he has conflict of interest because he DOES. His involvement with AHRQ and PROP are direct conflict that has been allowed to stand.

What you have done is genocidal. Anyone with compassion and common sense who actually CARES about pain pts would have separated the issues of addiction and pain because they are not the same, make a fearless search and development of non opioid , non pharma alts and in the meanwhile keep patients ON their opioid meds so they do NOT lose QOL and life its self. Pain patients could actually care less if an effective pain medication is an opioid or not. We are not here because we want opioids. We want relief. No one but a person in true pain would even think of putting themselves through the living hell we go through to obtain meds. It is a hell that no other patient goes through in obtaining proper care therefore it is abject discrimination against people in pain and disabled.

You MUST STOP this genocide and stop it now.

Sincerely,

Leah R. LoneBear
07/22/2020

From: GB LB
To: NCIPCBSC (CDC)
Subject: CDC GUIDELINES - COMMENTS
Date: Tuesday, July 28, 2020 9:36:49 PM

To Whom It May Concern:

I am writing you in regard to CDC guidelines implemented for intractable pain patients.

My daughter is disabled and has had 18 hip surgeries over 6 years leaving her disabled and in intractable pain for the last ten years. In addition to the 18 hip surgeries of which four have been total hip revisions has also had peripheral neurosurgeries for peripheral nerve damage.

Unfortunately the damage is more severe than science has evolved thus far to repair. There are additional surgeries that could be considered but risks outweigh the benefit as is no guarantee the pain would improve if not become worse from additional surgeries. Due to the already considerable intractable pain was not a risk could assume. Surgeons tell my daughter that they could try to repair the peripheral obturator nerve damage further but is no guarantee her condition would not get worse much less improve. She also has significant pelvic floor nerve involvement that has left her unable to sit more than 1.5 hours without severe discomfort.

My daughter has MBA and traveled globally launching IT software systems. During launch she would work 36 hours straight to support business functions while aiding employees troubleshooting issues and training. Most launch weeks would be lucky if obtained three hours of sleep every 36 hours. She would be onsite for months working 80 hour weeks if not longer during launch. Prior to launch behind the scenes worked with business areas tailoring software to meet the business end needs, writing process flows, and testing software. In addition to traveling for months on end was a triathlete, marathon runner, swimmer and figure skater. My daughter is a hard worker and has been working since was 13 years old. She was always on the go and completed more in one day than most do in a week or month.

Since was found had a congenial hip disease in her late 20’s while training for a marathon and her life has completely changed. The first hip had three open surgical reconstructions that rehabilitated for a year after each while continuing to work and complete daily functions. My daughter is strong and a fighter.

She had five reconstructive surgeries within eight months on the other hip. When the surgeon opened the other hip which initially thought to have less damage was found to be much worse than other hip. There were bone shards coming through the joint capsule

and labrum was obliterated. The hip was not formed properly from birth and had severe bone on bone impingement. The surgeon couldn't believe how remained so active prior to symptoms presenting and rapidly deteriorating. He initially thought had only bought her ten years until a hip replacement due to the damage. Unfortunately due to complications and the joint becoming unstable a hip replacement was ultimately required within a year.

After the initial hip replacement is when the majority of the problems began. Through this point pain medications were used only for postoperative pain and only for two weeks. Once the replacement was done my daughter cried and screamed throughout the night in pain. Pain was radiating through her back, leg, and had foot drop. I don't believe she remembers much of the initial pain in the months after the replacement as the brain has a way of protecting one from painful memories.

It was determined within months the surgeon had impinged the iliopsoas and adductor muscles leading to peripheral neuropathy. The replacement surgeon denied was an issue and left her to figure out the next steps as was beyond his scope of expertise.

It took months to find a qualified a surgeon in total hip reconstruction complications and complete diagnostics. Within eight months came up with a three surgical plan to repair impingements and damage caused from initial hip replacement. By that time the damage was done. After the three surgeries were completed she still could not walk without crutches and has severe gait dysfunction even with continued therapy. The surgeon said initial surgeon did a huge disservice leaving impingements for an extended period of time and damage was likely permanent. It was determined the implant was loose 18 months after initial THA. Upon retrieval was found the implant initially used was for an 80 year old woman not a young active woman in her late 20's.

The second revision was completed after 17 months as the bone again did not grow into the implant. This led to seeing multiple specialists and bone endocrinologists.

Hindsight is always 20/20 but having a hip replacement so young wished had taken heed of age and sought out a specialist who commonly did active younger women's total joint replacements. Even if meant exhausting savings to go out of state and staying six weeks for surgery and recovery.

By this time surgeon and other consulting doctors compared pain to bone cancer pain due to the lack of osteointegration, opaqueness, and lucidity of bone. Doctors said the implant is pistoning shearing bone nerve endings. She was started initially on breakthrough medication and could not get out of bed to complete functions of simple care. As a parent seeing your daughter who never complained nor gave up hope of a complete repair confined to bed in pain was horrific.

My daughter fought her doctors regarding the pain medication and refused to accept was permanently disabled. She believed a fix would become available and was reluctant to take medication. But it came down to the ability of some semblance of life and functionality.

Her surgeon has been supportive and wrote letters to the best complicated revision surgeons throughout the country in hopes of finding a surgeon who would take on her case. Unfortunately have found surgeons are graded on percentage of positive outcomes and were reluctant to touch the hip due to the volume of surgeries.

We traveled far and wide for consultations only to be told to amputate the leg or "hospice" care. The thing is with the hip, cannot easily amputate at the pelvis without severe complications and prosthesis fit is not likely for an adult.

Traveling is very hard for my daughter and can put her in bed for weeks after due to the long sit time, inability to stand, or walk for long periods of time.

We traveled to Johns Hopkins University in Maryland to see a peripheral neurosurgeon who completed three surgeries on the sensory branches of the obturator, saphenous, lateral cutaneous, and superior gluteal nerve branch to the right SI joint. Due to the gait dysfunction has sacroiliitis and the lower lumbar spine has deteriorated including herniated discs as well as degenerative disc disease.

During the time waiting for specialists to review history additional diagnostics were completed looking for additional causes of pain. With congenital hip disease is not uncommon to have inguinal hernias due to the structural damage to the hip. It was determined had inguinal hernias on both sides. Due to severe groin pain the surgeon only repaired the right inguinal hernia. Her surgeons and team of doctors said not to repair the left hernia until becomes an emergency as needs one leg to function. Due to the risk of nerve damage after a hernia repair all felt was a risk should not be taken. Unfortunately the hernia repair completed impinged the lateral cutaneous nerve again.

During this time was sent to pain management specialist who completed a fellowship in pain management and is a board certified anesthesiologist. He is a wonderful and compassionate doctor who cares about her wellbeing. He completed SCS and pain pump trials. She also completed years of biofeedback, pain therapy, acupuncture, dry needling, as well as physical therapy. He also writes up anesthesiology plans prior to all surgeries based on current peer reviewed studies to limit opioid use after surgery.

After the hernia repair trialed a SCS stimulator only to find interference from the device. Upon completion of MRI and myelogram found several herniated discs in the thoracic spine causing interference. Since thoracic herniations were not painful it was determined should not surgically repair due to the known complications of back surgery.

Pain pump trials were commenced which unfortunately did not provide relief. Was again sent out of state for a consult to implant paddles in the spinal canal. The neurosurgeon upon review of tests felt was still significant impingement from the implant and thought should be revised again in attempt to correct.

A peripheral neurosurgeon specialist moved into the area and was referred for a consult. There was a lesser repair completed on the obturator nerve from the pelvis and the lateral cutaneous impingement repaired again as the inguinal hernia surgery had unfortunately impinged the lateral cutaneous nerve for the second time.

Prior to the third revision Forteo was started three months prior to surgery and used in total for a year as prescribed by the bone endocrinologist. The bone endocrinologist wanted to have a year of Forteo remaining as would need another revision within her lifetime. Unfortunately did not believe the fourth revision would ultimately happen so soon.

After ceased Forteo was started on Prolia to protect bones as were concerned about osteopenia seen during third revision and was diagnosed with osteomalacia. Prolia caused an almost immediate reaction. She experienced widespread muscle and bone pain. This side effect was reported to the FDA and told not uncommon, to discontinue, and side effects could last for several years.

During this time hair started falling out, hand swelling, low grade fevers, rashes, along with widespread pain. Upon further testing with rheumatologist was determined had a postitive ANA and RNP. Once rheumatologic symptoms began after Prolia had first abnormal kidney values. Anti-inflammatoires had not been used recently. A kidney biopsy was performed and was found to have scarring from anti-inflammatory use which had been used sparingly over the years and received kidney function tests every six months while used. The kidney biopsy also showed had genetic disease, thin basement membrane disease. Skin biopsies revealed connective tissue disease.

The Lupus nephrologist advised could not use anti-inflammatories again for pain management. The rheumatologist was concerned as lupus is typically diagnosed before thirty years of age. Testing revealed severe particle shredding from multiple hip revisions. The theory is Prolia opened the osteoclasts and bone absorbed metal particles leading to an autoimmune disease. Currently is managed with steroids and hydroxychloroquine after multiple immunosuppressant trials.

Her othopaedic surgeon completed the fourth revision as over five surgeons had denied to see her and recommended modalities from palliative care, hospice to amputation. Amputation was determined to be too risky as mentioned. Fusion was no longer an option due to bone loss.

The anatomy is no longer anatomically correct. Due to the multiple revisions the acetabulum is about 4-5” higher than the native left hip. This caused severe atrophy and muscles not to fire due to structural imbalance. She cannot lift her right leg and is dead weight. Bone stock is severely depleted and if attempt another revision and doesn’t go well amputation may be the unfortunate consequence.

My daughter at times has been in so much pain was suicidal. Only once pain was managed properly did she obtain improved daily functionality as well as mental wellbeing. Although she is permanently disabled she is much happier and does not spend days in bed or avoiding visiting with friends and family due to intractable pain. I cannot stress enough the improvement on her quality of life.

In the past several years since the initial CDC guidelines were released did troubles start. Her doctors called pharmacists filling prescriptions detailing extensive medical history and why is on prescribed medication. She has been stable on her current protocol for over seven years. A new pharmacist at her local CVS pharmacy started questioning monthly medications. The pain specialist doctor would call monthly prior to prescriptions being filled to discuss treatment protocol with the pharmacist. The pharmacist didn’t question the doctor but questioned my daughter monthly and frequently delayed the filling of medication.

My daughter has followed yearly pain contracts, gone to all monthly appointments, pill counts, and urine testing without issue. The pharmacist was asked to review MAPS as has been stable on medications for years with the same pain management doctor. Her HIPAA rights have been violated to prove to the pharmacist medical necessity as to medications were prescribed obtaining pain control and quality of life.

Eventually switched to a small pharmacy that is familiar with her medical history and physician to avoid monthly issues. This shouldn’t be this hard with such a detailed and documented history. The FDA states are no limits on quantity or dose of pain medications in treatment of long term intractable pain.

The left labrum tore again due to overuse and had loose foreign bodies. Due to poor outcome from
THA, the reconstruction surgeon opted to do the fourth reconstructive repair hoping to put off THA until an appropriate age. She went into sepsis after surgery and couldn’t continue stronger immunosuppressants. While in the hospital the attending physician and nurses treating sepsis refused to give prescribed pain medication. The pain physician who is an anesthesiologist on staff at the hospital requested a pain management consult as was not rounding on days hospitalized. The surgeon also requested a pain management consult to no avail. The attending still refused to request a pain management consult. This is dangerous for several reasons. First we know is physically dependent upon medications and second withdrawal could be dangerous, if not fatal, if

medication is suddenly withdrawn. Finally her rheumatologist had her released early into her care as attending wasn't familiar with rheumatologic/orthopaedic history and were wanting to repeat recent diagnostic tests. This was a mistake but necessary due to lack of consistent treatment. Due to this the infection returned several times requiring seeing additional specialists: urologist and infectious disease.

The last year her insurance company denied the quantity of medication prescribed. She has had a prior authorization in place for seven years that has been renewed annually. The dosing and frequency of medication has not changed. The pain management doctor appealed this decision three times and was denied. Then appealed to the state board and was returned as is not on Medicare. Suddenly after appealing to the state received a letter of approval from the insurance company was received after four months not receiving medications as prescribed.

We saw a decline in functionality during this period and was again spending more time in bed. The doctor wrote a second prescription for the amount not covered by insurance after the first month and had to pay cash for the quantity not covered. What gives the insurance company the right to determine care over a board certified pain management doctor? This is also an additional financial burden to a permanently disabled individual on a fixed income. Not to mention worry if insurance company would decide to further restrict medication.

The data does not support intractable pain patients are contributing to the opioid crisis. Why have the CDC Guidelines been treated as law when are just that, guidelines? These guidelines have harmed more intractable pain patients than weeding out addicts. Buprenorphine was not determined to be useful for my daughter's case by multiple specialists. Many patients have been forced off medications or denied coverage by insurance. This is not humane and are seeing an increase of intractable pain patient suicides. Is that the unintended goal? Intractable pain patients are human beings and their lives also matter and have value.

My husband was in hospice during this time and hospice wouldn't prescribe morphine which was previously used by attending ICU doctors for two weeks to keep calm and not restless. When admitted to hospice medications were changed and ceased using morphine even though had a better response prior to being admitted to hospice. The reasoning? They didn't want to overdose a terminally ill hospice patient. He was non verbal due to septic shock and couldn't communicate but was clear morphine gave significant and improved comfort. The CDC guidelines are also impacting end of life comfort and care.

My daughter would happily share medical history and her doctors would discuss how these guidelines have negatively impacted care.

Please take the patient into consideration when reviewing these guidelines. These decisions should be between a patient and their doctor not a government agency that has never seen the patient. There are many unintended consequences and are permanently harming patients.

My apologies for a detailed email but the medical history needs to be taken into account when writing these guidelines. Any doctor familiar with her medical history or following my daughter for years understands the necessity of treatment. Once thoroughly review records is undeniable what has been through and continues to go through on a daily basis. These guidelines only make life harder on the patients without targeting those who are abusing opiates.

With Covid-19 has only become harder to receive required care due to being high risk. Please think of patients like my daughter when evaluating these guidelines. My daughter is fearful to advocate for herself for fear of retaliation. This is a sad state of affairs for all intractable pain patients and doctors who manage their care. What happens later in life when her current doctor retires? Will she be forced off her medication like other patients? Will she suffer in debilitating pain until she dies a painful death or worse?

Thank you for your time.

Sincerely,
Leslie Kusky

To: Board of Scientific Counselors of the CDC National Center for Injury Prevention and Control

Attn: Shannon Lee

From: Peggy Hillman (berner24@hotmail.com)

Re: Comments for July 22, 2020 Meeting regarding the 2016 Opioid Prescribing Guidelines Review/Opioid Workgroup

Date: July 28, 2020

I'm a patient with fibromyalgia and arthritis. I have to say that I am very disappointed and appalled to see zero patients appointed to the opioid workgroup that CURRENTLY require opioids to sustain their ability to function and who are experiencing the current struggles that patients face trying to obtain sufficient pain medication to live their best life since implementation of the 2016 opioid guidelines. Chronic intractable pain patients are the ones most impacted by these guidelines yet, once again, we are not voting members of the workgroup. Perhaps even more disappointing, FIVE members who contributed to the original 2016 opioid guidelines have been appointed to the workgroup. Given the extreme controversy regarding the 2016 opioid guidelines, it is completely unethical to include members from the original workgroup in the new workgroup, least of all appointed as the Chairman of the new group. I'm requesting that CDC immediately change the leadership of this group and replace anyone who had a part in the completion of the published 2016 opioid guideline as they cannot possibly be impartial and are likely to stand in the way of patient-centered care as recommended by the AMA, the HHS opioid task force, the FDA, patients, patient advocates, and hundreds of providers. The leader of this group should be a pain management specialist who is an opioid moderate with no conflicts of interest.

We know that the 2016 guidelines had a catastrophic impact on pain patients and their providers. The guidelines have been weaponized by nearly all regulators resulting in the torture, abandonment, and death of many patients including Carla Whittmore Howard and Dawn Anderson.* Carla (below, left) was force tapered and soon began having heart attacks. She had no underlying heart condition according to her cardiologist. She died suddenly from a fatal heart attack thought to be induced by severe pain. Dawn (right) was also forced off her meds. Multiple providers refused to treat her pain appropriately. The only way they would agree to treat her pain was if she stopped her dialysis and went onto palliative care. She could not live without the dialysis. She chose to die while having her pain treated rather than live in agony. These two deaths were

unnecessary tragic consequences of over-regulation driven by the weaponization of the CDC's 2016 opioid guidelines, a reality that CDC had been warned of prior to publishing the guidelines.

It is imperative that the current workgroup understand that one-size-fits-all will not work with patients. They must recognize that any guideline must be patient-centered and should never be used to assign fixed limits or prohibit prescribing to any patients. Prescribing goals should help the patient obtain the best quality of life possible with the least adverse reactions. Risks and benefits for each patient must be analyzed by taking into consideration the patient's biopsychosocial history and past treatment history as well as any genetic anomalies that might impact metabolism. While risk of addiction should be considered, it is equally important to consider the severe impact that undertreated and untreated pain has on patients. Insufficient pain relief can cause job loss, inability to perform activities of daily living (ADLs), economic instability, suicide, and sudden death as mentioned in the case of Carla Whittmore Howard above.

Even the rare patient who suffers from addiction deserves to have their pain treated appropriately. Addicted patients should not have to seek specialty providers to be treated. Any physician should be able to treat addiction and/or pain. If we truly want to end the stigma for these patients, they should have the same opportunities as everyone else. The less we treat them like lepers, the more likely they are to seek treatment and the less likely they are to die.

It is crucial that this workgroup not further stigmatize these already disenfranchised patients. I urge this group to consider a different approach to opioid therapy. These patients have been stigmatized and discriminated against by doctors, nurses, pharmacists, insurance companies, politicians, law enforcement, hospital administrators, media, Medicare/Medicaid, their friends and family, and the general public at large. This can only be resolved by providing equal treatment to all. This means changing the way we talk about opioid use. When discussing opioids, they're worth should neither be elevated nor devalued. Yes, one can become addicted but most will not. Truth matters. Fear mongering is not appropriate nor helpful. Opioids should be just one of many tools in the box and all tools should have equal value. It makes sense to approach in this manner because every patient is different. For many, opioids will not be the tool of choice. For others, it may be the only tool that provides any quality of life for the patient.

It is important that this workgroup remember that most legacy pain patients have tried and failed every treatment available and found only opioids allowed them any quality of life. For those patients, there is no other option. To deny these patients opioid treatment at a dosage that allows them to live their best life is to sentence them to torture and likely early death. It must be realized that this is a subset of patients who have no other option because they have literally tried everything. Any guidelines must account for these patients. Furthermore, the group must realize that this subset of patients who rely on opioids is not limited to legacy patients. There will be new patients who will eventually end up in this category no matter what treatment becomes available and affordable due to genetically modified pathways and rare manifestations of disease. The thought that multidisciplinary treatment can prevent this subset of patients from

needing opioids is wishful thinking as history proves this small subset of patients who only respond to opioids will always exist. These patients are not the norm but they do exist in significant numbers (approximately 20 million) and must be given the opportunity to live their best life possible.

I would strongly urge this workgroup to reconsider the goals of this group. It is clear that the only goal the 2016 opioid workgroup set was to reduce opioid prescribing. There was no post publication follow-up or concern for how these reductions impacted patient lives even though the group was told prior to publication their guidelines would negatively impact patients. Since when do we implement patient recommendations without follow-up? Who does that? They were told how they could reword the guideline to prevent catastrophic harm prior to publication yet no action was taken to make said changes. Furthermore, when harm was plainly evident, they waited three years before they issued a clarification that fell upon deaf ears and no other action was taken regardless of how many patient and provider lives were destroyed. Any and all future recommendations that impact patient care should be followed carefully and immediately remediated if proven to be harmful to patients.

Also of critical importance, this workgroup must realize that prescribed drugs did not cause and are not sustaining the overdose crisis. Seventy percent of OD deaths are due to heroin and illicitly manufactured fentanyl and its analogs therefore no regulation of prescription drugs or their supply chain will prevent overdose deaths driving this crisis. Furthermore, most OD deaths involve non-medical users, not patients. Children, their parents, and patients using controlled substances should be taught the signs of addiction and how to get help. For instance, a normal reaction to an opioid is to feel a dulling (not elimination) of pain and/or drowsiness. They should understand they should not experience feelings of euphoria when they take the opioids. If they have this experience, they will likely become addicted and should cease using the drug immediately and seek professional help if needed.

As public policy makers, a more ethical and practical goal would be to strive to reduce overdose deaths due to all drugs but particularly those responsible for the most deaths, currently heroin and illicitly manufactured fentanyl and its analogs. To do this, the primary focus will need to be on non-medical users as they represent the majority of those who are dying. If we really want to save lives, harm reduction such as Naloxone distribution and fentanyl test kits will need to be readily available to non-medical users. The single most important thing to remember is that an addict will always find another substance to abuse. There is already a newer, deadlier substance that is replacing illicit fentanyl in illicitly sold drugs thus the tools used to reduce harm would need to change periodically as the abused substances change over time. We cannot regulate our way out of this crisis. In fact, many (including me) would argue that over-regulation is what has caused this overdose crisis. Safe supply and addiction education that address the root problems of addiction are the keys to reducing deaths, not fear mongering and prohibition.

Finally, I'd like to remind this workgroup that we are talking about guidelines that impact the lives of 100 million patients and their providers. The goal should be to protect the patient and help

patients live their best lives possible. They must recognize that every patient is different and requires individualized care. While precautions should be taken to protect public health, it is essential that no policy restrict or eliminate ANY treatment that is essential for any individual patient to live their best life. This includes all pharmacological and non-pharmacological treatment with or without combination therapy. Furthermore, because of the harm from the original guideline on the autonomy of providers, it is essential that this workgroup ensure that regulators, particularly law enforcement and medical boards, are made to understand the goals of treatment and the importance of patient-centered care. This means that there can be no hard prescribing limits that are appropriate for every patient or even most patients as all patients react differently. Providers therefore can only reliably use the lowest EFFECTIVE dose for each patient as judged by ADLs and the quality of life of the patient. If these are not the goals of this workgroup, I insist this group disband immediately and refrain from further discussions regarding opioid prescribing that seek to impact patient care, rescind the 2016 opioid guidelines, and defer to the FDA which is the only entity legally allowed to determine prescribing guidelines for prescription drugs. Without exception, quantity and/or dosage of opioids prescribed should NEVER be considered a determining factor of success or malfeasance when patients are involved, as patient health and well-being are the only things that should dictate successful patient care.

*Pictures of Carla Whittmore Howard and Dawn Anderson have been released to the public.

CC: Senate HELP Committee, FDA, Diane Feinstein, Nancy Pelosi, Mitch McConnell, NIDA, NIH

References:

CDC Appoints New Opioid Workgroup for Guideline Update: https://www.painnewsnetwork.org/stories/2020/7/24/cdc-appoints-new-opioid-workgroup-for-guideline-update#disqus_thread

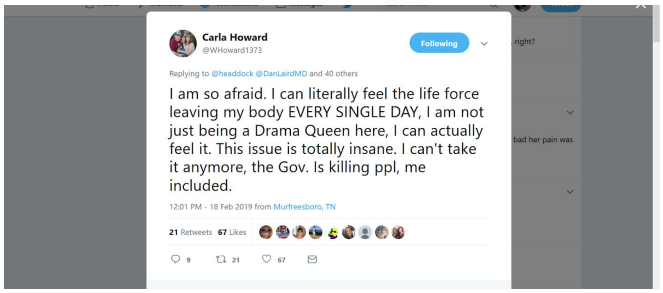
> “At least five members of the panel advised the CDC during the drafting of the 2016 guideline. They include the chair of the workgroup, Christina Porucznik, PhD, a professor of public health at the University of Utah, who chaired the opioid workgroup in 2016. Chinazo Cunningham, MD, Anne Burns, RPh, and Mark Wallace, MD, are also returning members of the workgroup. They are joined by Jeanmarie Perrone, MD, was a peer reviewer for the 2016 guideline.”

Opioid Workgroup 2020: https://www.cdc.gov/injury/pdfs/bsc/OWG-Roster-External-7-22-2020-FINAL.pdf?fbclid=IwAR2Wf_GC9-QF80KZwzIO1hOK9zgkoebLlbGOwGP7vioByyOkcMlZ0TB2tkM

Fentanyl and Heroin Linked to 70% of Overdoses:
https://www.painnewsnetwork.org/stories/2018/12/12/fentanyl-and-heroin-linked-to-70-of-overdoses?fbclid=IwAR3m0Ynmd_Wi0UQ4GNafE1QUQfqzlsoFavzvSzEU9HtBoe0JlhURCpOdHOY
Today's Non-Medical Users Are Not Yesterday's Patients...
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6369835/

National Vital Statistics Report:
https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_09-508.pdf

Tweet from Carla Whittmore Howard the day before her death:



Sudden, Unexpected Death in Chronic Pain Patients:
https://www.practicalpainmanagement.com/sudden-unexpected-death-chronic-pain-patients?fbclid=IwAR3E9x76J_8km6g9-F6gRWgoWECIuuowmOn5-UBsvzKpK5Atbjrp02KcWfQ

New Survey Data Confirm That Opioid Deaths Do No Correlate with Pain Pill Abuse or Addiction Rates:
https://reason.com/2019/08/21/new-survey-data-confirm-that-opioid-deaths-do-not-correlate-with-pain-pill-abuse-or-addiction-rates/?fbclid=IwAR01EeXzTvzO-dNHJ_8rwHV9z7AfQJoLKJB8QbHvXaYV10cVWuJZsEVCaus

Suicides Associated With Forced Tapering:
https://medium.com/@ThomasKlineMD/opioidcrisis-pain-related-suicides-associated-with-forced-tapers-c68c79ecf84d

Survey Finds Patients Are Harmed By CDC's Opioid Guidelines:
https://www.practicalpainmanagement.com/resources/news-and-research/survey-finds-patients-are-harmed-cdc-opioid-guidelines?fbclid=IwAR0Bs-R6PepSuR-mKZJaVMvygoFdvjpH6AjgPwqLIfec_nms4WuvAFLYrq8

From:	Liliana Calle
To:	NCIPCBSC (CDC)
Subject:	Fw: Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC/NCIPC) - Meeting, July 22, 2020
Date:	Wednesday, July 29, 2020 2:45:16 PM

Dear Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC/NCIPC)
Thank you for taking the time to address such important topics during July 22/2020 meeting. I would like to add the following comments:
Please consider reviewing the confidentiality law and allow Physicians to have access to information regarding MAT/methadone treatment. I am a professional counselor working in the field of addictions for the past 14 years. In my professional experience working with clients I observed that Clients usually do not disclose their full prescribed regimen to doctors and the Methadone information /prescription is unavailable to Doctors due to Federal confidentiality Laws, clients tend to obtain pain Medication from a nurse practitioner or from a PA. I have seen many overdoses caused because clients are overmedicated and doctors are not aware of the Methadone regimen the clients were prescribed.
A revision of the confidentiality law is absolutely needed to prevent overdoses, protect clients and to protect Doctors from Liability.
I appreciate the fact that you have a large group of Scientific Counselors however, I truly believe that diversity and inclusion is needed to reflect all the ethnic groups and other disciplines and opinions. We need to work on this task together to make sure our patients are safe and protected but at the same time we are providing timely and accurate information to clients.

In my opinion Pain medication should only be prescribed by a pain management specialist- A Board Certified Medical Doctor, not by a NP or by a PA.

Thank you for all you do.

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Gender Pronouns: She, Her, Hers, Ella

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From: NCIPCBSC (CDC) <NCIPCBSC@cdc.gov>
Sent: Tuesday, July 28, 2020 2:08 PM
Subject: Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC/NCIPC) - Meeting, July 22, 2020

Good afternoon Registrants –

This email is being resent to update the email address to submit written public comments in response to the July 22, 2020 BSC, NCIPC meeting. Please use the following address ncipcbsc@cdc.gov to submit your comments. In addition, the deadline for submission has been extended **until 5:00 PM July 29, 2020**.

We apologize for this error.

From: NCIPCBSC (CDC) <NCIPCBSC@cdc.gov>
Sent: Monday, July 27, 2020 1:19 PM
To: NCIPCBSC (CDC) <NCIPCBSC@cdc.gov>
Subject: Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC/NCIPC) - Meeting, July 22, 2020
Importance: High

Dear Registrants:

Thank you so much for your participation in the BSC meeting on July 22nd and appreciate your interest. We had many people who asked to make a public comment, but unfortunately we did not have sufficient time for everyone, who requested, to make a comment. Your comments are important to us and I want to remind you, as stated in the Federal Register Notice and at the BSC meeting, that we will be accepting written comments through **July 28th at 5 PM eastern time**. If you were not called upon, did not complete your statement in the time allotted, or have comments to share with us, whether or not you had pre-registered to express public comment, please send your comments to NCIPCBSC@cdc.gov . All comments will be included in the meeting minutes and will be considered in the same manner as we consider oral feedback.

Thank you again for your interest and participation.

Arlene Greenspan, DrPH, MPH, PT
Associate Director for Science
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

4770 Buford Highway, MS F63
Atlanta, GA 30341

From:	Lynne Hall
To:	NCIPCBSC (CDC)
Date:	Tuesday, July 28, 2020 3:06:14 PM

I along with the 50 million other chronic pain patients, have repeated begged for our rights to be treated humanly.
Peaceful protest, etc.
It is now clear to America that only your adgenda will be heard.
I have stated my case, repeatedly called Lindsey Graham. Nothing.
We all know we will be forced to die in pain. You have made sure of that by hurting our doctors.
But all of us pain patients have a plan for how we will end our lives. On our terms.
There will be a reckoning for your greed. Taking away our rights.
My parents didn't plan on a sick child, no one does. Do what you will but you have never looked at the other side of the opoid crisis honestly. May God have mercy on your souls.
You have taken away our quality of life without going thru proper channels.
Only the rich are allowed relief.
Karma is a bitch. May your family be healthy. Let them fight out wars and be hurt.
Momma's money only goes so far, once you too are dead.
Even abortion gets equal and fair reporting.
NO ONE TRUST THE CDC!

From: chavezmarth@msn.com
To: NCIPCBSC (CDC)
Subject: Pain Management
Date: Wednesday, July 22, 2020 8:23:24 PM

To Whom it May Concern:

It was early March of this year that I began having mild back pain that later turned intolerable within a span of 3 weeks. After calling my primary care physician, I was referred to the Kaiser Spine Center. I was prescribed ibuprofen and tylenol, topical lidocaine and was given a regimen of physical therapy exercises to do at home. After two weeks into this regimen I saw no improvement and the medication made me feel sick (I was told to take the maximum amount allowed for each medication). The pain became so severe I went to the ER where I had an MRI done. I was finally diagnosed with Lumbar Spondylosis, Stenosis of the Intervertebral foremen (moderate), a herniated disk and Lumbar Radiculopathy. I was released from the ER with no pain medication other than the one ibuprofen I was given during the 3 hours I was there. From here, it took another two weeks to get an appointment with the Nurse Practitioner back at the Spine Center where I was prescribed steroids and more NSAID's. I didn't get much relief and had stomach issues and head pressure after taking so much NSAIDs (I have a history of bleeding issues with NSAIDs, it's in my medical chart). After not getting any better I was referred to Pain Management. There, I was prescribed, over a period of time, 3 anti depressant medications, that I was not able to tolerate, more physical therapy, topical medication and began going to accupuncture. None of these helped. I called crying in pain one day and asked if I could please get something stronger as the medications and physical therapy and acupuncture were not really alleviating my pain. I told the doctor how I would practically spend my days on my back on the icepack until it melted and them switched it our for another one. I literally had to freeze my back numb to get some temporary pain relief. Also the pain was on both sides of my lower body and even came around to the front of my abdomen. I told her that I had to pee standing in the shower instead of the toilet because I couldn't sit in that position as the pain become more excruciating. I couldn't drive, walk or sit or lay down for any period of time. The pain was constant and severe. She asked me which medication I wanted. I said Norco, as I have taken this for pain in years past with no issues. She said "we don't do opioids here" and I was pegged as an 'opiod seeker'. It is in my medical record. My pain level remains. My four appeals to Kaiser and one to the Medical Board have been denied due to CDC guidelines. I have stopped going to pain management as they told me there wasn't anything more they could do for me. I was given the choice of getting spinal injections but at this time there is a 3 month wait. I feel that I have been betrayed and abandoned by the medical system. My future looks very uncertain. I was working full time as an elementary school teacher and I actually felt relieved when schools were closed and was sent to work from home because of Covid but even then, it was difficult to teach and get around the house because of the severe pain. At this point, I feel useless and abandoned. At 43 I wonder if this will be the rest of my life and I'm wondering if it's going to be worth living. The focus has strayed so far from compassionate care, do no harm or actual

pain management to a focus on pill counts all around the country. This has caused in my opinion, to overlook the heroin and fentanyl crisis that is to blame for overdoses as it has been reported that prescribed pills alone rarely cause overdoses. As someone who has been denied to access to medication that would improve my quality of life, I find it inhumane to remove opioids for pain relief as an option, when we really don't have another medication that is as safe and effective for long term use. I have begun to smoke cannabis (which I hate) but it's the only thing that I have found that alleviates the pain. I hate how it makes me feel as I will not be able to function in any sort of job in that state of intoxication. I would like for you to reconsider your guidelines so that they are purposeful and compassionate for managing pain and for people who need addiction treatment as well. As it stands, no one is getting the treatment they need and many lives are being destroyed by such a blanket policy. The CDC is full of PHDs, MDs, MAs and so on. I still find it puzzling that nobody could have anticipated the catastrophic consequences of removing opioids from pain management when there aren't any other medications or treatments that have been studied or proven as effective as opioid medications for alleviating pain and restoring quality of life for people. Please, please consider the plight of the pain patient as you consider rewriting the guidelines. Please restore the doctor patient relationship so that doctors can treat patients without fear of retaliation. Thank you for your time. By the way, I am not being payed by anyone. I am just advocating for myself.
M.Chavez

From: Maggie Buckley
To: NCIPCBSC (CDC)
Subject: Comments & Feedback on Public Meeting 7/22
Date: Monday, July 27, 2020 8:10:40 PM

As a person living with pain, I want to offer comments regarding last week's CDC Public Meeting, Opioid Workgroup Membership & New Stakeholder Input Opportunity.

I live with the genetic connective tissue disorder Ehlers-Danlos Syndrome Hypermobility Type and related comorbidities which have both acute and chronic pain issues.

For decades people living with pain have been limited to two options of pain management through our healthcare system; pills or procedures. After the release of the 2016 CDC Opioid Prescribing Guidelines, those two options were further limited due to the unintended adoption of the guidelines by state and local legislatures and even more restrictive reimbursement restrictions on the part of payors.

This created additional barriers for people to receive pain management care through the healthcare system. The barriers further widened the socioeconomic and racial disparity gaps between those who are able to access care and people who are denied care or receive limited care. The cutbacks in care have had heartbreaking consequences of death due to inappropriate withdrawal of medications, increase in mental heatlh issues, and even suicide as the ultimate pain relief option.

My hope is that the current efforts to revised the CDC Opioid Guidelines will do several things:

1. Underscore the need for people who have been receiving long term chronic pain treatment including opioid medications to continue with a proven treatment.

2. Recognition that effective pain management, in line with the HHS Pain Management Best Practices Report issued in 2019, is individualized.

3. Recognition that effective pain management, in line with the HHS Pain Management Best Practices Report issued in 2019, is most effective with multiple modalities in play.

4. Support of a transition to the standard of care being Comprehensive Integrative Pain Management (CIPM) in regulatory, legislative, CMS and payor models so that all pain management treatment options are regularly available for healthcare providers to employ in the care of people with acute and chronic pain.

With the inclusion of Kate Nicholson, Christine Goertz and Beth Darnell on the new workgroup. I am confident that a CIPM approach will be included in the deliberations of the workgroup. The inclusion of people who have lived with acute and chronic pain themselves has been a much needed step to be taken to effectively update the guidelines.

Respectfully,

Maggie Buckley

Maggie Buckley, MBA, BCPA
Walnut Creek, CA
Buckley.Maggie@gmail.com

From: Mark Stultz
To: NCIPCBSC (CDC)
Subject: Acute and Chronic Pain Comment
Date: Tuesday, July 28, 2020 4:21:09 PM

Thank you for the opportunity to make a public comment in regard to **Docket Number: CDC-2020-0029.**

I am a physical therapist who has spent the bulk of the past 30 years treating pain, with nearly 20 years committed to the management of pain using neuromodulation with a specific focus on the role for percutaneous peripheral nerve stimulation (PNS). Until the recent FDA-clearance of less invasive, non-permanent and less expensive options, PNS had been used only as a treatment of last resort at the end of the care continuum.

The provision of percutaneous peripheral nerve stimulation as a non-opioid treatment has a significant potential role to play for those who may find themselves on opioids and unable to stop using without another alternative that can bridge them to a life beyond opioids. There is a significant opportunity to use these FDA-cleared treatments to help manage pain and reduce post-operative pain and opioid use earlier in the care pathway. The risk of post-operative opioid addiction begins as early as day 5 post-op and becomes significant at day thirty. Patients need and are begin denied access to non-opioid options earlier in the care continuum. Neuromodulation devices, especially those that are non-permanent, can be particularly helpful as non-opioid alternatives.

The existing arbitrary, vague, overly simplistic and outdated definition of chronic pain as that which has endured for at least 90 days has many physicians withholding the treatment of opioid-sparing alternatives such as percutaneous PNS due to fear of claw-back by Medicare. At present, Medicare covers PNS for the treatment of chronic pain, but the definition of chronic pain warrants additional clarity that could encourage its earlier and appropriate use.

Consider the specific case of total knee arthroplasty (TKA), a very high-volume procedure performed in over 700,000 patients in the US each year. For those patients unfortunate enough to have severe pain at 6 weeks post-op, pain will remain severe at 6 months in 80%[*]. While the use of minimally-invasive and reversible FDA-cleared treatments can be very appropriate before 90 days post-op, physicians will not use them due to fear of claw-back. If the definition of chronic pain was clearer, treatments of this type could be readily implemented earlier and opioid use, diversion and addiction could be minimized.

Please consider a definition of chronic pain that facilitates the early and appropriate use of FDA-cleared treatments such as percutaneous PNS that includes any one of the following three conditions:

- *Pain that persists or recurs for longer than 3 months from its initial onset (temporal definition), or*
- *Persistent pain that, at the discretion of the physician, has not resolved within the normal time course of healing, or,*
- *Pain associated with opioid use that has endured beyond 30 days.*

[*]Hadlandsmyth, K, et al, The Clinical Journal of Pain: April 2018 Vol 34(4) p332-338

Thank you for your consideration. I am happy to make myself available anytime for further dialogue on this topic.

Mark R. Stultz, PT, MS
SPR Therapeutics, Inc.
612.770.0390

June 5, 2020

To Whom it may Concern:

I would like to provide individual comments on your request on the use of opioids in the management and treatment of those who suffer with pain. I have been involved in the management of pain for over 30 years and am dedicated to optimal care of those with pain at any time throughout their lifespan. I have concentrated my efforts on providing the best possible treatment available for the individual patient. I have had the good fortune of working in the clinical setting, e.g. in-patient, out-patient, acute therapy, chronic therapy and have also been included in the home setting for both pain relief and palliative care.

I would recommend your inclusion of information regarding the appropriate use of any opioid. Each patient is an "N" of one and should be treated as such. There may be times when all that is needed is an anti-inflammatory, but there may be times when an opioid is prudent and necessary. The importance of a single medication should be based on the relationship between a patient and his/her health care provider. The relationship may also include the caregiver in certain situations, as well as other health related specialists. There is no need to eliminate the use of opioids if they are the right option for the person in need.

I recognize the concern around the use of opioids and of using an opioid indiscriminately, but also realize there may be times when each pain option or therapy is made available to a certain individual. I ultimately recognize and support the use of all modalities, which may include what is currently viewed as both Eastern and Western medicine. I support the use of anything that is of value to the individual.

Thank you for your consideration of these comments. I am happy to provide additional information should you feel that would be helpful.

Respectfully submitted,

Marsha Stanton, PhD, RN

3152 Kittrick Dr

Los Alamitos, CA 90720

732-770-7997 cell

mstanton@painadvocate.com

From: Mary kotuba
To: NCIPCBSC (CDC)
Date: Tuesday, July 28, 2020 11:12:02 AM

I have 3 incurable diseases or conditions. I worked full time on pain meds for 20 years. I lived as close to a normal life as one could with 3 incurable, pain causing diseases.

Off of pain meds for 5 years, the VA increased my disability rating, & social security approved me in 2 months. Off pain meds, I developed high blood pressure, severe depression, had multiple trips to ER requiring surgery for broken bones & stitches from falling.

I have never had to go to an Emergency Room in my life until the stopping of pain meds. I fall much more with no help for pain.

I served 20 years in the Marine Corps & Naval Doctors at Bethesda Naval hospital experimented on me. They told me I had 1 of the highest pain tolerances the team had ever seen. Most Veterans have higher pain tolerances, so by the time we ask for help, it is bc we've already tried acupuncturists, masseuses, healers, mattresses, pillows, physical therapists, etc...we have the highest Veteran Suicide rates in American history because Vets are being ignored when they ask for help with pain.

If I didn't become an addict during the 20 years I took pain meds, WHEN, pray tell, was I going to become addicted?

I have a damaged spinal cord, syringomelia, & a rare, genetic, upper motor neuron disease. Addiction is the least of my concerns.

At least Addicts have HOPE of recovery. I have no hope & because of you, I lost all hope for relief from constant pain.

I hope you all are diagnosed with an incurable disease one day, because it will be the only way you will understand. Cancer is not the only disease on earth that causes intractable pain. I hope you come to comprehend that in a very personal way.

Mary Kotuba
724 480 6335
128 Addis Ave
Beaver Falls, la 15010

From: Michelle Stifle
To: NCIPCBSC (CDC)
Subject: CDC Guidelines 2020
Date: Tuesday, July 21, 2020 11:05:10 AM

Dear Sirs and Madams
I have been a chronic pain patient for 20 years. I have had 5 total knee replacements on right and 4 total hip replacements on left. I also have had infection in thoracic vertebra.
My journey has been life threatening and long. I was treated for pain at first very cautiously then as pain progressed so did the opioids to meet the growing needs from my progressive debilitating condition.
I was a healthcare worker for 20 years and after thoracic osteomyelitis I had to quit.
Now the pain doctor I see is afraid to prescribe enough to give me quality of life.
He is afraid of the DEA attacking his practice and taking away his livelihood.
The 90mme's make it impossible to cover most severe chronic pain. The state I live in is 50mme's. I have no quality of life. Going to the store or physical therapy is impossible due to pain. Just to stand up causes pain so bad I have to sit back down immediately
I don't understand the guidelines put forth. How can a doctor practice with compassion and caring with these restraints and fear. I have been on all the different meds over the years. However opioids have given me some comfort. Enough to keep me non suicidal.
Please, please change the guidelines. Increase the control of the pain management doctor to treat as needed. Some people may be able to work and live.
Sincerely
Michelle S.

From: Michelle Wilson
To: NCIPCBSC (CDC)
Subject: Life after CDC guidelines
Date: Friday, July 24, 2020 7:57:40 AM

All I want is to be able to take care of my family I have been luckier than most in that all my meds have not been taken away but have been decreased my long term med was totally taken from me and the short acting decreased from 4 to 3 times a day while only someone who lives with chronic pain will truly understand this has decreased my QOL especially when the weather is bad or a front is moving through on these days I can barely get out of bed I have been going to the same place for PM for six years but the practice has changed hands during that time so it looks on paper as if I changed PM Dr I fall into the at risk category due to my history of addiction to crack 9 yrs ago but I went through a four month inpatient rehab program and have passed every drug screen since I don't take these stupid pills because I WANT to if all my issue could be taken care of some other way I would jump on it so fast I shouldn't be forced to settle for a low QOL because people are illegally obtaining narcotics and then OD'ing they will find a way even if you took every narcotic out of circulation so you are punishing those like me while offering every ounce of help possible for those people that are breaking the law this seems so backwards I feel like I am living in the twilight zone thank you for listening to us now let's see if you are truly hearing us

Sent from my iPhone

Via Electronic Submission

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Phone 847/375-4714
Fax 847/375-6424
Web site: www.neuromodulation.org

July 29, 2020

Gwendolyn H. Cattledge, Ph.D., M.S.E.H
Deputy Associate Director for Science
CDC National Center for Injury Prevention and Control
4770 Buford Highway, NE, Mailstop S106–9
Atlanta, GA 30341

RE: Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC)
Request for Comments – Opioid Workgroup

We, the undersigned members of the North American Neuromodulation Society Advocacy Committee, applaud the Centers for Disease Control's opening of docket request CDC-2020-0029 and the Board of Scientific Counselors, National Center for Injury Prevention and Control public meeting and solicitation for stakeholder comments on acute and chronic pain management. A long-term solution to the opioid epidemic cannot be achieved without addressing the challenges of more effectively treating chronic pain. We look forward to working collaboratively with you to ensure pain patients have access to the full spectrum of treatment options to reduce pain, opioid related harms, and improve function.

Pain care is at a critical crossroads in America, and the need for updated guidelines and educational materials for patients and providers has never been greater. A 2019 Harris Poll of primary care physicians found increasing concerns about the challenge of appropriately treating pain patients and insufficient provider training in pain management. Of doctors polled, 83% reported that the opioid crisis makes it harder to treat pain patients, and 81% of doctors are hesitant to accept new pain patients. The COVID-19 pandemic will only increase these concerning statistics.

Our society, and many of our physician members, provided written comments to CDC-2020-0029 for your review. We write today to encourage the Opioid Workgroup and the Board of Scientific Counselors, National Center for Injury Prevention and Control to include the following key recommendations in any forthcoming CDC guidelines and educational materials for pain management:

- Adopt well-researched interventional pain guidelines – Evidence-based pain interventional therapies can and must play a larger role in effective pain management and efforts to reduce opioid related harms. A thorough data analysis will demonstrate robust clinical evidence supporting interventional therapies ability to reduce pain, improve function and reduce oral medications.

- Expand CDC educational materials for non-opioid treatments – Updated patient and clinician resources are necessary to improve awareness and utilization of proven alternative therapies, especially FDA approved treatments and technologies.

- Encourage earlier patient referrals to pain specialists – Currently, specialists are often not involved early enough in diagnosing and treating pain syndromes, which can lead to suboptimal patient outcomes. (cite evidence from Nilesh)

- Include HHS Pain Management Best Practices Inter-Agency Task Force recommendations, particularly section 2.4 Interventional Procedures in CDC guidelines – The Task Force's recommendations provide an essential blueprint for balancing the need to effectively manage pain and reduce the opioid misuse crisis.

We also respectfully request that the CDC hold a follow-up joint meeting with the leadership of our society as well as those from other leading organizations who have submitted comments, so that the CDC can hear directly from key opinion leaders about advancements in pain management, the multidisciplinary approach to reducing pain and improving function, and the evidenced-based technologies and therapies we utilize to improve outcomes and patient lives.

Our membership recognizes that the millions of Americans currently living with chronic pain as a result of a myriad of diseases, conditions and serious injuries, are a vulnerable population of individuals who are often underserved and stigmatized for the very real problem of chronic pain.

Updated CDC guidelines and pain educational materials would represent enormous progress towards effectively managing the complex and costly consequences of pain, including its impact on the opioid crisis. We collectively urge the CDC to meet with us to help you develop forward-thinking and appropriate recommendations. We may be contacted through our staff via the following email address: cwelber@neuromodulation.org

We look forward to hearing from you.

Respectively submitted,

David Provenzano, MD
Co-Chair NANS Advocacy and Policy Committee

Joshua Rosenow, MD
Co-Chair NANS Advocacy and Policy Committee

David Kloth,MD
Sr. Advisor, NANS Advocacy and Policy Committee

From: Joy Maxwell
To: NCIPCBSC (CDC)
Subject: Oregon Pain Patient's
Date: Wednesday, July 29, 2020 4:50:44 PM

Please help me I so wish I had the job I worked in for almost 25 years. I tried but my body just stopped me , with spinal stenosis arthritis in my spine hips. I went through so many treatments and so many medications. The last 22 years I finally had the prescription pain medicine that worked was on same dose same medication. I also had vitamins and herbal that ALL worked enough for me to have a productive life. I worked PT went to grandkids activities volunteered for the VFW . Then your guide lines for 2016 put a forced off of ALL my prescriptions NO tapered just was cut off I now am mostly bedridden I just want to have my productive life back. Please I have so much more to give I am praying that you the CDC revamp guide lines and also why can't the CDC grandfather in the Millions that were on prescription pain medicine like myself most were on same medication same dose for 15,20 plus years. Thanks for listening and taking the time to read this

Sent from my iPhone

To: Board of Scientific Counselors of the CDC National Center for Injury Prevention and Control

Attn: Shannon Lee

From: Peggy Hillman (berner24@hotmail.com)

Re: Comments for July 22, 2020 Meeting regarding the 2016 Opioid Prescribing Guidelines Review/Opioid Workgroup

Date: July 28, 2020

I'm a patient with fibromyalgia and arthritis. I have to say that I am very disappointed and appalled to see zero patients appointed to the opioid workgroup that CURRENTLY require opioids to sustain their ability to function and who are experiencing the current struggles that patients face trying to obtain sufficient pain medication to live their best life since implementation of the 2016 opioid guidelines. Chronic intractable pain patients are the ones most impacted by these guidelines yet, once again, we are not voting members of the workgroup. Perhaps even more disappointing, FIVE members who contributed to the original 2016 opioid guidelines have been appointed to the workgroup. Given the extreme controversy regarding the 2016 opioid guidelines, it is completely unethical to include members from the original workgroup in the new workgroup, least of all appointed as the Chairman of the new group. I'm requesting that CDC immediately change the leadership of this group and replace anyone who had a part in the completion of the published 2016 opioid guideline as they cannot possibly be impartial and are likely to stand in the way of patient-centered care as recommended by the AMA, the HHS opioid task force, the FDA, patients, patient advocates, and hundreds of providers. The leader of this group should be a pain management specialist who is an opioid moderate with no conflicts of interest.

We know that the 2016 guidelines had a catastrophic impact on pain patients and their providers. The guidelines have been weaponized by nearly all regulators resulting in the torture, abandonment, and death of many patients including Carla Whittmore Howard and Dawn Anderson.* Carla (below, left) was force tapered and soon began having heart attacks. She had no underlying heart condition according to her cardiologist. She died suddenly from a fatal heart attack thought to be induced by severe pain. Dawn (right) was also forced off her meds. Multiple providers refused to treat her pain appropriately. The only way they would agree to treat her pain was if she stopped her dialysis and went onto palliative care. She could not live without the dialysis. She chose to die while having her pain treated rather than live in agony. These two deaths were

unnecessary tragic consequences of over-regulation driven by the weaponization of the CDC's 2016 opioid guidelines, a reality that CDC had been warned of prior to publishing the guidelines.

It is imperative that the current workgroup understand that one-size-fits-all will not work with patients. They must recognize that any guideline must be patient-centered and should never be used to assign fixed limits or prohibit prescribing to any patients. Prescribing goals should help the patient obtain the best quality of life possible with the least adverse reactions. Risks and benefits for each patient must be analyzed by taking into consideration the patient's biopsychosocial history and past treatment history as well as any genetic anomalies that might impact metabolism. While risk of addiction should be considered, it is equally important to consider the severe impact that undertreated and untreated pain has on patients. Insufficient pain relief can cause job loss, inability to perform activities of daily living (ADLs), economic instability, suicide, and sudden death as mentioned in the case of Carla Whittmore Howard above.

Even the rare patient who suffers from addiction deserves to have their pain treated appropriately. Addicted patients should not have to seek specialty providers to be treated. Any physician should be able to treat addiction and/or pain. If we truly want to end the stigma for these patients, they should have the same opportunities as everyone else. The less we treat them like lepers, the more likely they are to seek treatment and the less likely they are to die.

It is crucial that this workgroup not further stigmatize these already disenfranchised patients. I urge this group to consider a different approach to opioid therapy. These patients have been stigmatized and discriminated against by doctors, nurses, pharmacists, insurance companies, politicians, law enforcement, hospital administrators, media, Medicare/Medicaid, their friends and family, and the general public at large. This can only be resolved by providing equal treatment to all. This means changing the way we talk about opioid use. When discussing opioids, they're worth should neither be elevated nor devalued. Yes, one can become addicted but most will not. Truth matters. Fear mongering is not appropriate nor helpful. Opioids should be just one of many tools in the box and all tools should have equal value. It makes sense to approach in this manner because every patient is different. For many, opioids will not be the tool of choice. For others, it may be the only tool that provides any quality of life for the patient.

It is important that this workgroup remember that most legacy pain patients have tried and failed every treatment available and found only opioids allowed them any quality of life. For those patients, there is no other option. To deny these patients opioid treatment at a dosage that allows them to live their best life is to sentence them to torture and likely early death. It must be realized that this is a subset of patients who have no other option because they have literally tried everything. Any guidelines must account for these patients. Furthermore, the group must realize that this subset of patients who rely on opioids is not limited to legacy patients. There will be new patients who will eventually end up in this category no matter what treatment becomes available and affordable due to genetically modified pathways and rare manifestations of disease. The thought that multidisciplinary treatment can prevent this subset of patients from

needing opioids is wishful thinking as history proves this small subset of patients who only respond to opioids will always exist. These patients are not the norm but they do exist in significant numbers (approximately 20 million) and must be given the opportunity to live their best life possible.

I would strongly urge this workgroup to reconsider the goals of this group. It is clear that the only goal the 2016 opioid workgroup set was to reduce opioid prescribing. There was no post publication follow-up or concern for how these reductions impacted patient lives even though the group was told prior to publication their guidelines would negatively impact patients. Since when do we implement patient recommendations without follow-up? Who does that? They were told how they could reword the guideline to prevent catastrophic harm prior to publication yet no action was taken to make said changes. Furthermore, when harm was plainly evident, they waited three years before they issued a clarification that fell upon deaf ears and no other action was taken regardless of how many patient and provider lives were destroyed. Any and all future recommendations that impact patient care should be followed carefully and immediately remediated if proven to be harmful to patients.

Also of critical importance, this workgroup must realize that prescribed drugs did not cause and are not sustaining the overdose crisis. Seventy percent of OD deaths are due to heroin and illicitly manufactured fentanyl and its analogs therefore no regulation of prescription drugs or their supply chain will prevent overdose deaths driving this crisis. Furthermore, most OD deaths involve non-medical users, not patients. Children, their parents, and patients using controlled substances should be taught the signs of addiction and how to get help. For instance, a normal reaction to an opioid is to feel a dulling (not elimination) of pain and/or drowsiness. They should understand they should not experience feelings of euphoria when they take the opioids. If they have this experience, they will likely become addicted and should cease using the drug immediately and seek professional help if needed.

As public policy makers, a more ethical and practical goal would be to strive to reduce overdose deaths due to all drugs but particularly those responsible for the most deaths, currently heroin and illicitly manufactured fentanyl and its analogs. To do this, the primary focus will need to be on non-medical users as they represent the majority of those who are dying. If we really want to save lives, harm reduction such as Naloxone distribution and fentanyl test kits will need to be readily available to non-medical users. The single most important thing to remember is that an addict will always find another substance to abuse. There is already a newer, deadlier substance that is replacing illicit fentanyl in illicitly sold drugs thus the tools used to reduce harm would need to change periodically as the abused substances change over time. We cannot regulate our way out of this crisis. In fact, many (including me) would argue that over-regulation is what has caused this overdose crisis. Safe supply and addiction education that address the root problems of addiction are the keys to reducing deaths, not fear mongering and prohibition.

Finally, I'd like to remind this workgroup that we are talking about guidelines that impact the lives of 100 million patients and their providers. The goal should be to protect the patient and help

patients live their best lives possible. They must recognize that every patient is different and requires individualized care. While precautions should be taken to protect public health, it is essential that no policy restrict or eliminate ANY treatment that is essential for any individual patient to live their best life. This includes all pharmacological and non-pharmacological treatment with or without combination therapy. Furthermore, because of the harm from the original guideline on the autonomy of providers, it is essential that this workgroup ensure that regulators, particularly law enforcement and medical boards, are made to understand the goals of treatment and the importance of patient-centered care. This means that there can be no hard prescribing limits that are appropriate for every patient or even most patients as all patients react differently. Providers therefore can only reliably use the lowest EFFECTIVE dose for each patient as judged by ADLs and the quality of life of the patient. If these are not the goals of this workgroup, I insist this group disband immediately and refrain from further discussions regarding opioid prescribing that seek to impact patient care, rescind the 2016 opioid guidelines, and defer to the FDA which is the only entity legally allowed to determine prescribing guidelines for prescription drugs. Without exception, quantity and/or dosage of opioids prescribed should NEVER be considered a determining factor of success or malfeasance when patients are involved, as patient health and well-being are the only things that should dictate successful patient care.

*Pictures of Carla Whittmore Howard and Dawn Anderson have been released to the public.

CC: Senate HELP Committee, FDA, Diane Feinstein, Nancy Pelosi, Mitch McConnell, NIDA, NIH

References:

CDC Appoints New Opioid Workgroup for Guideline Update: https://www.painnewsnetwork.org/stories/2020/7/24/cdc-appoints-new-opioid-workgroup-for-guideline-update#disqus_thread

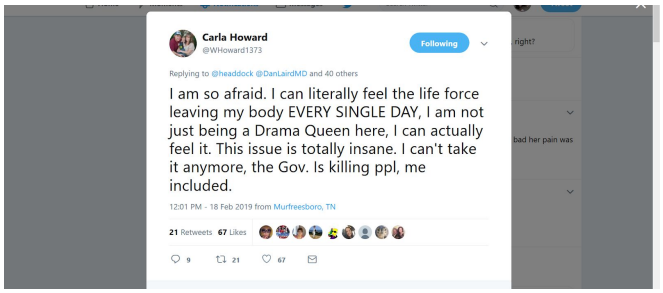
> “At least five members of the panel advised the CDC during the drafting of the 2016 guideline. They include the chair of the workgroup, Christina Porucznik, PhD, a professor of public health at the University of Utah, who chaired the opioid workgroup in 2016. Chinazo Cunningham, MD, Anne Burns, RPh, and Mark Wallace, MD, are also returning members of the workgroup. They are joined by Jeanmarie Perrone, MD, was a peer reviewer for the 2016 guideline.”

Opioid Workgroup 2020: https://www.cdc.gov/injury/pdfs/bsc/OWG-Roster-External-7-22-2020-FINAL.pdf?fbclid=IwAR2Wf_GC9-QF80KZwzIO1hOK9zgkoebLlbGOwGP7vioByyOkcMlZ0TB2tkM

Fentanyl and Heroin Linked to 70% of Overdoses:
https://www.painnewsnetwork.org/stories/2018/12/12/fentanyl-and-heroin-linked-to-70-of-overdoses?fbclid=IwAR3m0Ynmd_Wi0UQ4GNafE1QUQfqzlsoFavzvSzEU9HtBoe0JlhURCpOdHOY
Today's Non-Medical Users Are Not Yesterday's Patients...
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6369835/

National Vital Statistics Report:
https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_09-508.pdf

Tweet from Carla Whittmore Howard the day before her death:



Sudden, Unexpected Death in Chronic Pain Patients:
https://www.practicalpainmanagement.com/sudden-unexpected-death-chronic-pain-patients?fbclid=IwAR3E9x76J_8km6g9-F6gRWgoWECIuuowmOn5-UBsvzKpK5Atbjrp02KcWfQ

New Survey Data Confirm That Opioid Deaths Do No Correlate with Pain Pill Abuse or Addiction Rates:
https://reason.com/2019/08/21/new-survey-data-confirm-that-opioid-deaths-do-not-correlate-with-pain-pill-abuse-or-addiction-rates/?fbclid=IwAR01EeXzTvzO-dNHJ_8rwHV9z7AfQJoLKJB8QbHvXaYV10cVWuJZsEVCaus

Suicides Associated With Forced Tapering:
https://medium.com/@ThomasKlineMD/opioidcrisis-pain-related-suicides-associated-with-forced-tapers-c68c79ecf84d

Survey Finds Patients Are Harmed By CDC's Opioid Guidelines:
https://www.practicalpainmanagement.com/resources/news-and-research/survey-finds-patients-are-harmed-cdc-opioid-guidelines?fbclid=IwAR0Bs-R6PepSuR-mKZJaVMvygoFdvjpH6AjgPwqLIfec_nms4WuvAFLYrq8

From: Peter Pischke
To: NCIPCBSC (CDC)
Subject: Comment for CDC & Federal Register
Date: Monday, July 27, 2020 11:30:29 PM

Hello,

This message is a comment for the Board of Scientific Counselors, National Center for Injury Prevention and Control, (BSC, NCIPC); CDC July 22nd meeting, https://www.federalregister.gov/documents/2020/07/06/2020-14447/board-of-scientific-counselors-national-center-for-injury-prevention-and-control-bsc-ncipc-amended

Dear CDC,

My name is Peter Pischke and I'm an independent journalist, pain patient advocate and an intractable pain patient myself. Recently I've been published with Pain News Network, and I've also done health reporting for the Federalist and other news organizations.

There are many more researched experts better than I can give you the statistics proving the 2016 CDC guidelines have created nothing short of health-care disaster not seen in more than a century. Doctors Lawhern, Tennant, Singer & others have submitted excellent comments and should be taken seriously.

My experience with the guidelines is multi-fold. As a journalist, I've covered their effect on the country and individuals. As an advocate, I've counseled dozens in the last year that have been severely negatively impacted by the guidelines as they've been doctor abandoned, maligned, and essentially left to die. As an intractable pain patient and a disabled man, I've felt the pain firsthand dying from having lost access due to the guidelines and not having anyone or anywhere in society to go to for help. In many ways I've gained key experience both professionally and personally to know of which I speak.

In 2008 I came down with my first pancreatic attack. Discovering I had chronic pancreatitis turned out to be quite lifechanging. My high school senior year got canceled & I had to try it all over. Plans for the future were at first delayed and then eventually canceled altogether. Personal difficulties were plenty, but there was at least one element in my favor: my doctor and pain treatment.

My family doctor took my concerns seriously and treated me seriously. He prescribed pain meds including tramadol and oxycodone to deal with the pain. With his help and advice, I managed to complete high school, attend a full-time Church of Jesus Christ of Latter-Day Saints mission, and eventually graduate journalism school with a bachelor's from SDSU. Eventually, i would also finish graduate school to obtain my Masters in the same. This good doctor with the help of opioids was able to save my life, not just my health but also my future.

That changed however after the 2016 CDC guidelines when in 2018 I got told by my doctor that despite knowing me personally and treating me for a very long time that they would be ending my pain treatment. My doctor at that point had cut down their pain patients to just 2 people, and despite knowing we needed the medicines; this doctor wasn't willing to sacrifice their career to keep prescribing me the pain meds I needed to survive and thrive.

My life and future essentially stopped, as my ability to function turned to barely being able to get out of bed each day. My dreams for a wife and family of my own ended with them.

My life is physically very challenging, and I'll honestly be surprised if I'm still kicking in 20 years. Losing access to opioids hurt me incredibly and turned me from a chronic pain patient with few comorbidities to an intractable patient with many. My life is often a living hell and that is all thanks to the good folks at the CDC.

Yet, my experience under the 2016 guidelines is surprisingly meal compared to the many patients I've communicated and counseled with. Tales of suicide, liver failures, and homelessness are common. Most patients were not only denied medication but also had their medical reputations ruined by doctors putting in lies in their EHCR to justify dropping them. Often personal reputation and familial damage follow.

The 2016 CDC Guidelines did create the opioid prohibition, no doubt. But they also enabled a gigantic cohort of overwhelmingly poor and disabled patients to be abandoned not just by their doctors; but also by society. Wit the guidelines came a moral crusade that pitted addicts against pain patients. And 9/10 patients lost.

The physical, but also emotional and spiritual damage you've done to many millions of innocent law-abiding Americans is unfathomable. Deaths, family disintegration, poverty, addiction and suffering are the consequences of the guidelines.

This moral abomination as far as I've studied the matter, is mostly to do with good experts making very bad judgments that the rest of government and society ran with. Yes, PROP definitely earns their culpability, and engaging any of them in the CDC for any reason is dangerously naive but it was the good people at the CDC that enabled them.

It behooves the workgroup and the CDC to put forward new guidelines that completely repudiate the 2016 guidelines. The AMA and many other physician representative organizations are in agreement with me on this. The guidelines must be repudiated and done so in a very bold manner.

Because the state legislatures and Congress ran with the pronouncements of the guidelines, the opioid prohibition has finagled it's way throughout government both federal, state, and local. The only possible way to undo the damage without taking 20 years to do it, is for the CDC to resoundingly push back against the opioid prohibition and the 2016 guidelines.

Put the patient-doctor relationship back together. Allow patients their live-saving medications back. Do not withhold medication from the disabled. Let us have our health and our lives back. Perhaps one-day opioids will be unnecessary, but that is not this year and unlikely to happen for a very long time. Please do not punish the innocent for your mistakes.

Repent and undo the 2016 guidelines,

Respectfully but prayerfully,
- Peter Pischke

From:	Richard Lawhern
To:	NCIPCBSC (CDC)
Subject:	Comment on NCIPC Board of Scientific Advisers Meeting July 22, 2020
Date:	Tuesday, July 28, 2020 3:41:43 PM

As requested in your recent email update, I am resubmitting the following comment for inclusion in the minutes of the July 22 2020 meeting. Although I was pre-registered to address the meeting and was dialed in, my name was not called. Some of those who were called had not pre-registered. This was a violation of your own published rules for speaker selection, which creates an appearance of cherry picking less effective or less well known critics of the CDC process and published work. I request confirmation of receipt of this message.

For the meeting minutes:

Three Minutes to Change the World
Richard A. Lawhern, PhD
Comment to the Board of Scientific Counselors
Of the CDC National Center for Injury Prevention and Control
July 22, 2020

Good day. I am Richard A. Lawhern, PhD, a co-founder of the Alliance for the Treatment of Intractable Pain. I am a non-physician patient advocate with 24 years experience in this field and over 90 published articles and papers. I speak on behalf of millions of pain patients who have been profoundly and needlessly damaged by the 2016 CDC Guidelines on prescription of opioids. I have no financial conflicts of interest.

As this body deliberates on revision of the CDC guidelines, you must embrace these facts:

- The US Agency for Healthcare Research and Quality informs us that there are no profiling instruments that accurately predict risks of opioid dependency, tolerance, or addiction in individuals. However, as they fail to inform us, there never will be.

- Genetic polymorphism in P-450 series liver enzymes that metabolize opioids generates a wide natural range of minimum effective dose. Case reports indicate some patients are helped by as little as 20 MMEDD, while others benefit from over 2000 MMEDD — without significant side effects, sometimes for periods of years.

- Over-prescribing did not create our US opioid “crisis.” Dr Nora Volkow, Director of NIDA, tells us “addiction is not a predictable outcome of opioid prescribing.” Risk of addiction to medically managed opioids is less than 1%. Overdose mortality is three to six times higher in youth under age 24 than in seniors over age 62. But prescribing in seniors is three to six times higher than in youth. U.S. states with higher prescribing rates have overdose mortality rates below the national average. These demographic inversions give the lie to the notion that doctors "over-prescribing" to pain patients *ever* contributed significantly to the bogus "opioid epidemic".

- The American Medical Association has repudiated MMED as a measure of risk or benefit, and characterized “high prescriber” letters as a blacklisting of doctors and their patients, violating legal due process. Denial of pain care when it is available constitutes patient abuse and desertion.

It is time to admit publicly that the 2016 CDC guidelines were not only misapplied, but wrong on facts, science, and medical ethics. Contrary to the narratives of fringe element anti-opioid zealots and their insurance company sponsors, medically managed opioid analgesics are safe, effective and indispensable. For millions of pain patients, no effective alternative treatments exist.

This is a re-submission in response to your request below:

Richard A "Red" Lawhern PhD
Twitter: @Lawhern1
Facebook: https://www.facebook.com/red.lawhern
My Publications: http://www.face-facts.org/Lawhern
Personal Website: http://www.lawhern.org

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Good afternoon Registrants –

This email is being resent to update the email address to submit written public comments in response to the July 22, 2020 BSC, NCIPC meeting. Please use the following address ncipcbsc@cdc.gov to submit your comments.

We apologize for this error.

From: NCIPCBSC (CDC) <NCIPCBSC@cdc.gov>
Sent: Monday, July 27, 2020 1:19 PM
To: NCIPCBSC (CDC) <NCIPCBSC@cdc.gov>
Subject: Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC/NCIPC) - Meeting, July 22, 2020
Importance: High

Dear Registrants:

Thank you so much for your participation in the BSC meeting on July 22nd and appreciate your interest. We had many people who asked to make a public comment, but unfortunately we did not have sufficient time for everyone, who requested, to make a comment. Your comments are important to us and I want to remind you, as stated in the Federal Register Notice and at the BSC meeting, that we will be accepting written comments through **July 28th at 5 PM eastern time**. If you were not called upon, did not complete your statement in the time allotted, or have comments to share with us, whether or not you had pre-registered to express public comment, please send your comments to NCIPCBSC@cdc.gov . All comments will be included in the meeting minutes and will be considered in the same manner as we consider oral feedback.

Thank you again for your interest and participation.

Arlene Greenspan, DrPH, MPH, PT
Associate Director for Science
National Center for Injury Prevention and Control

Centers for Disease Control and Prevention
4770 Buford Highway, MS F63
Atlanta, GA 30341

From:	Samantha Adcock
To:	NCIPCBSC (CDC)
Subject:	Fwd: Comments CDC Guidelines Acute & Chronic Pain
Date:	Tuesday, July 28, 2020 11:09:41 AM

---------- Forwarded message ---------
From: **Samantha Adcock** <hope411adcock@gmail.com>
Date: Tue, Jul 28, 2020, 10:02 AM
Subject: Comments CDC Guidelines Acute & Chronic Pain
To: <NCIPCBS@cdc.gov>

Thank you for your interest in how the False Opioid Crisis has effected patients with chronic & intractable pain diseases.

I am both a caregiver and an intractable pain patient. So my story is somewhat complex and two-fold.

In addition to having several chronic pain conditions my daughter has a heart condition & a seizure disorder.

She had been established with a PM for 4 yrs until he sold his practice. When the practice sold she was discharged because she requested to have an appointment directly after they returned from lunch so that she wouldn't have to sit 3-4 hrs waiting for her appointment.

There were several times that we would apply lidocaine to her entire body in preparation for a procedure & by the time they took her back it had worn off & her pain level was then too high to proceed.

They scheduled her for a procedure in 2 weeks. A week later she received a letter in the mail notifying her that she had been discharged with a 30 day RX.

She ended up in the ER due to withdrawal because 30 days was insufficient to titrate off 2 high dose Opioids.

Her PCP got her into another PM. He reinstated her RX at the previous levels. But told her that in order to continue she would have to see a Neurologist as well.

She said that's fine, I have an appointment with my neurologist in 2 months. That wasn't good enough. He required that she see a Neurologist before her next refill appointment in 1 month.

I got her in with 2 weeks. When she returned for her refill appointment the PM refused to refill her opioid RX.

Stated "I know that you need them, but my license is more important & I'm too scared of the DEA to prescribe what you need."

At the time he discontinued her Opioids she was on 25mcg patch every 3 days & 4mg dilaudid every 4 hrs (180 month).

Her "Titration" dose was:

0 - Fentanyl

42 - Dilaudid

Week 1 - 1 3×day

Week 2 - 1 2xday

Week 3 - 1 1×day

Week 4 - 0

He didn't even bother to discuss her titration with her. The 1st we knew of it was after he left the office and the nurse was handing me her RX.

Needless to say I was extremely concerned about the safety of such an extremely rapid taper given her heart condition & seizure disorder.

I expressed my concerns to the nurse. When she checked with Dr no adjustments were made.

He had told her that if her neurologist would write a letter stating that the treatment plan was appropriate he would reinstate it.

So, I took her back to the. Neurologist who examined her, said the treatment plan was appropriate & that they would send the letter.

My daughter began having 10-15 seizures a day. Made multiple trips to the ER. The ER Dr's were appalled that she had been tapered so rapidly & stated that they wouldn't even taper someone off of heroin that fast.

My daughter has a home health provider through the state. As her condition continued to deteriorate the home health nurse was recommending that I consider Hospice since she was unable to eat due to the constant pain & seizures.

Even after receiving the letter from the neurologist, being notified of the seizures & contacted by the ER Dr's her PM refused to either reinstate or adjust the titration.

I got her into her PCP who RX'd long enough to get her to a new PM who made her choose between the patch & the Dilaudid.

She chose the Dilaudid. He has subsequently Involuntarily reduced her dosage without so much as discussing it with her.

The reduction is discovered when she goes to pick up the RX & the quantity is different.

I know this is a lot of information. If you would like to discuss my story as well.

Please feel free to give me a call at 501-530-1550

Samantha Adcock

My story begins back when PROP 1st began manipulating public opinion with deceptive press releases & buried data in 2007.

From: Samir Sheth
To: NCIPCBSC (CDC)
Subject: Interventional Pain Inclusion
Date: Tuesday, July 28, 2020 3:50:15 PM

To Whom It may Concern:

I am a double Board Certified in Anesthesiology and Pain Physician, Pain Fellowship trained pain physician. I have also served as a faculty member at UC Davis for 8 years where I was Director of Neuromodulation as well as Director of Resident and Student Education. I am now at Sutter Health in Northern California but still at UC Davis as a volunteer clinical faculty. I am also on the Board of Directors for Pacific Spine and Pain Society (PSPS) and am on the Policy and Education committee for the North American Neuromodulation Society (NANS) Finally, I serve as a consultant for the Medical Board of California. I have lectured and taught on cadavers for the last 10 years, and have been involved with extensive research in Pain Management including several multicenter randomized trials seeking to decrease pain, improve function and decrease the need for opioid medications.

I have taken care of many patients at both academic centers and in community settings and have used a multitiered approach for my patients including many of those advocated by the CDC in its 2016 guidelines (Physical therapy, gabapantenoids, antidepressants, Tai Chi, acupuncture). Unfortunately, the practice of pain medicine is complex and not black and white. In fact, I strongly feel that it is a combination of many therapies that are most effective for patients. Specifically, in addition to the above, the careful and judicious use of FDA approved interventional pain treatments (radiofrequency neurotomy, spinal stimulation, intrathecal pumps, regenerative therapies, epidural steroids, vertebral augmentation) is warranted given their safety and efficacy as evidenced by numerous randomized controlled trials. More importantly, I have seen amazing results first hand and while anecdotal data is just that, I am fortunate to have miraculous stories to share about these outcomes. Therefore, I request the inclusion of the HHS Best Practices Section 2.4 (Interventional Pain Procedures) to be fully included in the forthcoming CDC guidelines.

It is also important for the CDC to encourage early referrals to pain medicine physicians given that delay in treatment is more likely to lead to opioid prescription writing as well as to treatment resistance to therapy. Early use of interventional pain treatments have the best chance of decreasing pain and opioid use.

Finally, I humbly request that interventional pain physicians be appointed to the Board of Scientific Counselors for Injury Prevention and Control, and the opioid Work group tasked with advising the CDC and decreasing opioid overdose and deaths. Considering the advent of newer highly effective therapies for pain patients, it would be very beneficial to the committee and more importantly our patients to ensure access to these therapies.

Sincerely,
Samir J Sheth, MD

From: Sarah B
To: NCIPCBSC (CDC)
Subject: Public Comment
Date: Tuesday, July 28, 2020 3:46:35 PM

To whom this may concern,

I'm writing to make a public comment in response to the BSC meeting on July 22nd. I am a chronic pain patient and have been for roughly eight years. My care has changed drastically since the 2016 CDC guidelines. My doctors have been afraid to prescribe opioids or to prescribe them at the levels that will ease my pain. Luckily, I have found some good doctors but my pain is not being managed well because of these guidelines. I was recently told that my dosage could not be increased unless I do some injections or other procedures at their office because "they don't like to see us increasing dosages without doing other procedures." I have done every single procedure out there, just at a previous pain management office. Now I'm going to have to retry all of these procedures to be able to get my medication to a level where I am being fully supported.

Reliable pharmacies have been extremely difficult to find since 2016. One day, I went to 9 different pharmacies trying to get my opioid prescription filled. I actually wasn't able to get it filled that day because none of the pharmacies either had the quantity or would fill my prescription because they have other patients who who are regulars and they were holding their stock for them. Or I was simply told they didn't have it, which you can never know if that's the truth. It is very difficult that I cannot call the pharmacy and see if they have the medication that I have been prescribed. I have to physically go to the pharmacy, which as a chronic pain patient is not an easy feat and severely increases my pain.

I have been on opioids for about seven years now and they have been the only thing that really takes my pain away. I still keep up with physical therapy, I have a spinal cord stimulator implanted, I have had other back surgeries and procedures. But the one thing that always helps is opioids. I have never had any issues with taking my prescriptions as they are written and feel I'm being punished for other people's mistakes. Sometimes opioids are just needed and our doctor should not be afraid to prescribe them, or prescribe them at a level that is managing the pain well and our pharmacies should not be afraid to carry them and to fill the prescriptions of their customers.

Please consider making some specific recommendations for primary care physicians and ensure that it is very clear that pain management physicians are not included in these guidelines. 55 mg morphine equivalent is written as a suggestion but every doctor I've been to has taken it as if it is law. I am able to keep a full-time job, and I would not be able to do this if I did not have access to an opioid prescription. Because of opioids I am a taxpaying and positively contributing member of this society. I hope that you will look at this from the perspective of a chronic pain patient and consider that when writing the 2021 guidelines. This directly affects so many people's lives, those of us who are in chronic pain, the least that can be done is give us access to medication that takes that pain away or lowers that pain in any way. If I was unable to access opioids and thus unable to work, it would affect my entire family, my future, my self-esteem. Those of us that are in chronic pain already have to deal with enough, the last thing that we should have to be dealing with is worrying about getting access to the medication that was created to reduce pain and that reduces our pain.

The chronic pain community has been severely affected by the 2016 guidelines and I hope that that can be reversed in the 2021 guidelines.

Thank you,
Sarah Buchan

From:	Sean Savarese
To:	NCIPCBSC (CDC)
Subject:	War on pain patients
Date:	Tuesday, July 28, 2020 11:13:21 PM

End your complicity in the war on pain patients. Besides being the height of hypocrisy, immorality, and futility, it has wrecked havoc on an absolutely unprecedented scale.

Although powerful interests groups, motivated by gain and not by individual or collective well being, have instigated this continuing atrocity, it is not sustainable. More and more people I interact with can smell a rat: they see this destructive propaganda and the policies instituted as a result for the outrageous sham that it is.

Sean

July 28, 2020

Board of Scientific Counselors, National Center for Injury Prevention and Control
NCIPIC CDC
4770 Buford Highway, NE
Mailstop S106-9
Atlanta, GA 30341

Re: **Comments on the Department of Health and Human Services (HHS) Public Health Service Board of Scientific Counselors (BSC) Centers for Disease Control and Prevention (CDC) National Center for Injury Prevention and Control (NCIPC) Thirty-Third Meeting**

Dear Board of Scientific Counselors,

Voices for Non-Opioid Choices ("Voices") appreciates the opportunity to submit comments on the proceedings of the HHS Public Health Service BSC CDC NCIPIC. Voices is a nonpartisan coalition dedicated to preventing opioid addiction before it starts by increasing patient access to non-opioid therapies and approaches to managing acute pain. Our coalition is fully invested in doing our part to help curb the U.S. opioid epidemic by advocating for and ensuring that patients are educated and informed about all available, safe, and effective options to treat acute pain, especially after surgery. Our approximately 40 members include licensed healthcare professionals such as physicians, nurses, dentists, therapists, and related associations as well as patient advocacy groups, students, individuals in recovery, and retirees.

Voices believes that it is important to ensure that people who are in recovery from opioid use disorder have access to non-opioid options when faced with the prospect of having surgery. On average, patients receive 80 opioid pills to manage pain following a surgical procedure, which is well above what is necessary to help these patients adequately control their symptoms.[1] Every year in our country, three million Americans become persistent opioid users following surgery, meaning they are still taking these medications three to six months after their surgical intervention.[2] Unfortunately, some of these users will go on to develop substance use disorder and never recover.

We have heard countless stories of individuals (as well as members of our coalition) who have lost children, spouses, and friends, among others, to an addiction that developed after surgery. They often stress to us that they did not know that there were other options to manage their loved one's acute

[1] Bicket M, et al. Prescription opioid oversupply following surgery. Journal of American Pain Society 2017.
[2] Brummett CM, Waljee JF, Goesling J, et al. New Persistent Opioid Use After Minor and Major Surgical Procedures in US Adults. JAMA Surg. Published online June 01, 2017152(6): e170504. doi:10.1001/jamasurg.2017.0504

pain. We also hear from individuals in recovery who need to have surgery, but who are too afraid to do so, because they are worried about relapse post-surgery.

To close the surgical gateway, we need guidelines that offer procedure-specific, standardized, non-opioid driven multimodal approaches to manage patients' acute pain throughout their surgical journey.

In our work with providers across the country, we often hear significant issues with the lack of standardized surgical protocols with an opioid-sparing focus. Enhanced Recovery After Surgery (ERAS) protocols are multimodal perioperative care pathways designed to meet that need – by achieving early recovery after surgical procedures by maintaining pre-operative organ function and reducing the profound stress response following surgery. ERAS protocols include preoperative counseling, optimization of nutrition, standardized analgesic and anesthetic regimens and early mobilization. This type of recovery focuses on avoiding prescribing opioids after surgery. Studies have shown that ERAS protocols can significantly reduce opioid consumption post-surgery and improve patient outcomes.[3,4,5] Most recently, the American College of Surgeons released data showing a 60 percent reduction in opioid use during a patients' stay in the hospital following the implementation of an ERAS protocol in bariatric surgery.[4]

Furthermore, there are already existing HHS recommendations by the Pain Management Best Practices Inter-Agency Task Force that support ERAS and standardized, procedure-specific multimodal therapies that we believe BSC should refer to while considering guidance around acute pain management. The following recommendations would help manage acute pain through a standardized multimodal protocol with minimal to no opioid use[6]:

- ***Recommendation 1A:*** Use procedure-specific, multimodal regimens and therapies when indicated in the perioperative period, including various non-opioid medications, ultrasound-guided nerve blocks, analgesia techniques (e.g., lidocaine, ketamine infusions), and psychological and integrative therapies to mitigate opioid exposure.
- ***Recommendation 1B:*** Use multidisciplinary and multimodal approaches for perioperative pain control in selected patients at higher risk for opioid use disorder (e.g., joint camps, Enhanced Recovery After Surgery [ERAS], Perioperative Surgical Home [PSH]). Key components for optimal pre-habilitation may include preoperative physical therapy (PT), nutrition, and psychology screening and monitoring; preoperative and postoperative consultation and planning for managing pain of moderate to severe complexity; preventive analgesia with preemptive analgesic non-opioid medications; and regional anesthesia techniques, such as continuous catheter-based local anesthetic infusion.
- ***Recommendation 2A:*** Encourage public and private stakeholders to develop acute pain management guidelines for common surgical procedures and trauma management, carefully

[3] Meyer, LA, et al. Effect of an Enhanced Recovery After Surgery Program on Opioid Use and Patient-Reported Outcomes. Obstetrics & Gynecology Aug 2018 Volume 132 Issue 2 p281-290

[4] Hoehn RS, et al. Enhanced Recovery Protocol for Laparoscopic Sleeve Gastrectomy: Are Narcotics Necessary? J. Gastrointest Surg. 2019 Jan 28 p1-6

[5] Simpson JC, Bao X, Agarwala A. Pain Management in Enhanced Recovery after Surgery (ERAS) Protocols. Clin Colon Rectal Surg. 2019 Mar; 32 (2): 121-128

[6] Pain Management Best Practices Inter-Agency Task Force Final Report on Best Practices: Updates, Gaps, Inconsistencies and Recommendations: Retrieved on July 22, 2020 from: https://www.hhs.gov/ash/advisory-committees/pain/index.html

considering how these guidelines can serve both to improve clinical outcomes and to avoid unintended negative consequences.

These recommendations could prevent acute pain from turning into long-term chronic pain, which poses a significant economic burden for health systems and societies. In addition, these recommendations are a great step in closing the surgical gateway to opioid addiction.

We appreciate your consideration of our comments and would be glad to discuss further. Please contact me at shanta@nonopioidchoices.org if you have any questions. We look forward to your continued work on solving the crisis and stand available to answer any questions.

Sincerely,

Shanta Whitaker, PhD MPH
Director, Scientific Affairs
Voices for Non-Opioid Choices

From: Shirley Buck
To: NCIPCBSC (CDC)
Date: Wednesday, July 29, 2020 6:39:52 PM

Thank you for the opportunity to comment anyway. Big disappointment not being able to during the session.

I am a Domestic Violence Survivor
Multiple cervical and thoracolumbar spine fractures and crushed sacrum/coccyx bones
I've had two cervical surgeries and still live in horrible pain and require a hard brace many days each month as well as a lumbar brace each month. I also live with extremely bad RLS which is in my arms and legs. Without opiate medication I would not sleep at all. I have tried Every RLS drug available and nothing works, nothing other than opiates. I believe it is a very sad world we live in where our govt decides what a doctor can & cannot prescribe. Without my medication I can guarantee you I will not make it more than a couple days. It is honestly that bad. I've tried taking myself off. I knew exactly what I was getting into when I had to start being medicated, my doctor made very sure of it. I've lived this way for 20 years and I'd love to see my 3 grandsons grow up. My children are in fear of what will happen to me if my medication is taken away as I raised them alone. I'm 54 years old, I'm not out on the streets buying or selling drugs I'm at home with my grandsons and dogs who force me to have to walk and continue to be active. I'm not a couch potato, I love life. I've had the same PM doctor for 15 years, they know me. No dirty UAs. No early refill requests, Never Any Issues. I can't even find a Neurosurgeon to touch my lumbar spine because "I'll end up in a wheelchair". Every single one says my med needs to be increased, I laugh and say, the govt took care of that, its suffering now. I just want for our doctors to be able to treat us as individuals and APPROPRIATELY medicate us. It isn't like the PDMP isn't available for the DEA & DOJ to see what docs are prescribing erratically and stop them. So others have to suffer? PLEASE RECONSIDER THESE GUIDELINES. THIS IS TRULY INHUMANE TORTURE. WE ARE HUMAN BEINGS. I NEVER ASKED TO END UP LIKE THIS, IT WAS DONE TO ME. ARE YOU ALL GOING TO MAKE MY LIFE EVEN WORSE. ITS ALMOST LIKE ITS ENTERTAINMENT OBVIOUSLY FROM DR.BALLANTYNES BEHAVIOR AND RESPONSES. She was obviously extremely unprofessional and an embarrassment to her colleagues. That cannot be denied. PLEASE PLEASE RECONSIDER THESE 90 MME and all limits. The PDMP allows you to see everything. What more do you need. What has happened to our country where our government tortures its taxpaying citizens. WE ARE DYING FROM THIS. PLEASE PLEASE I BEG YOU TO PLEASE HELP US. PLEASE.

Thank You and God Bless You.

From:	Stacey Fields
To:	NCIPCBSC (CDC)
Date:	Tuesday, July 28, 2020 3:53:37 PM

Hello

Patients have been telling you that what you are doing is harming them since this began in 2016. You say our feedback matters but clearly it does not. I run a group for chronic pancreatitis patients,(over 3800 members) we have lost 4 to suicide due to not having effective pain care. Others have turned to alcohol which WILL kill them since they have a bad pancreas. Still, others have turned to street drugs. You talk about sprains, lower back pain and fibromyalgia but nothing about MS, Pancreatitis, Lyme, CRPS and many other VERY painful conditions. I wish you could experience the pain these conditions cause then maybe you would understand just how much harm you are causing. For women on the task forces imagine being in labor 24/7, 365 days a year! The men involved should have to experience this as well, maybe with simulated pain for days on end. If you have never experienced any of these conditions you have absolutely no clue how painful they truly are. People have lost hope and many more are contemplating suicide to escape the pain you are forcing them to live in. You have said this is about addiction yet the states (all of whom received millions from the gov) are cutting funding to addiction services. The CDC has already admitted they skewed the numbers and the AMA has spoke out and told you you are wrong in what you are doing. What is it going to take to get any of you to have some ethics and stop this madness? -- We no longer go to the E.R. when we clearly need to, this almost cost me my life and if I had gone when I should have they surely would have caught the cancer sooner, stage 3C colon cancer! This is the most unethical discriminating policy of my lifetime and it horrifies me to think my children and grandchildren will be forced to live in horrific pain at the hands of the very people trained to help us. Many of us will no longer have any medical procedures because we are afraid and this will flow into the public that are not ill as soon as they get mistreated by the medical people whose hands you have tied. Maybe then we will see protests over this that get out of hand and cause the sort of damage we are seeing right now. Colonoscopies without anaesthesia, no pain care after a double mastectomy or no pain care for cancer patients, how can you justify this? All of this WILL cause more death and despair all at your hands. We can only hope that someone will come to their senses soon. Pain IS and still should be the 5th vital sign as it is a sign that something is WRONG in our bodies. People will stop getting proper medical care and the medical industry will suffer big money losses. We are tired of suffering and will not support those who don't support us. I know this is falling on deaf ears but I need to say it again even if no one is listening! You have also thrown science out the window all on the word of a self-appointed opioid expert who knows NOTHING about these diseases or the pain they cause but clearly that doesn't matter either! As I said before this is the worst policy of my lifetime and I do not understand how you people can do this to your fellow Americans who are struggling to live and have ANY quality of life.u must know the increase in suicides is directly related to people not having proper pain control but hey that doesn't matter either does it? Thousands have died at YOUR hands! Have you all forgotten the days of Waverly and other institutions where psychiatrist abused patients horribly? This is another rendition of those days of horrific suffering and death.

--

Stacey Fields
The National Chronic Pancreatitis Support Network

 Pancreatitis....Pick up the fight!

From: Stacey Turiello
To: NCIPCBSC (CDC)
Subject: Comment Opioid Workgroup Meeting July 22, 2020
Date: Wednesday, July 29, 2020 6:02:51 PM

CDC Comment for July 22, 2020 Meeting Opioid Workgroup

Stacey Turiello, patient, Ambassador Chronic Disease Coalition

I am a patient with severe high impact chronic pain with multiple diagnoses. I currently live with undertreated pain due to the misapplication of the 2016 CDC Guidelines by the DEA. First and foremost, it is difficult to explain the profound, encompassing, negative effects of the 2016 CDC Guidelines. They have had, unintentionally or not, the effect of moving the medical specialty of pain management into pre-modern times and have caused patient harm on a prodigious scale, with patients being abandoned by physicians who fear regulatory attention, patients being force tapered and perhaps most profoundly, have eroded the doctor-patient relationship that is sacred and necessary for providing appropriate ongoing pain care. Per the CDCs numerous assurances, patient and provider outcome data was to be obtained with the release of the guidelines four years ago. Since then, we have seen not a single attempt to obtain any outcome data by the CDC. It appears the only outcome data the CDC is choosing to use is the metric of number of opioid prescriptions. This is obviously unreliable due to the vast nuances involved in individual care. Without context of medical history, comorbidities, genetic metabolism variance, and other factors obtained by physician autonomy, the sheer number of opioid prescriptions is irrelevant. There are a vast number of patients whose lives are improved by using long-term opioid therapy, including mine. Without a suitable substitute, we have entered a medical dark age in which patients are forced out of medical care for their diagnoses and disabilities and left to suffer needlessly, alone in pain. Many patients turn to self-medicating with licit or illicit substances or suicide, which have increased more significantly than overdoses due mostly to illicit substances and polypharmacy since the release of the guidelines. I fear an expansion or revision of the guidelines will only increase the harm to patients. We should not have to choose between integrative care with non-opioid options. Patients should have all options of pain modalities available, and work with their own physicians to create and achieve their own goals of function and pain control and plans to reach those goals as realistically as possible.

I agree with the American Medical Association in repudiating the metric of morphine milligram equivalent (MME) or morphine equivalent daily dose (MEDD), and arbitrary numerical limits on opioid levels, and with their comment on the expansion/revision of the guidelines. Reputable scientific evidence shows a 15-fold genetic variance in opioid metabolism with all other variables being equal. We do not need a one-size-fits-all federal guide. As we have seen, federal guidance, intentional or not, is regarded as law. In fact, the CDC did not act as 34 states legislated some or all of the guidelines into state law. These misapplications will take generations to undo. The expansion/revision of the current guidelines will prove to have expanded detrimental effects of patient harm and increased suicides.

Any federal guidelines are supposed to protect patients, however, the 2016 CDC Guidelines have not only not protected patients, but have actively and directly inflicted immeasurable harm through using arbitrary limits that were conjured using weak to very weak science and repudiated by the AMA, specifically in the House of Delegates Resolution 235.

The myopic lens the CDC tends to view patient issues through is harmful in that it excludes the context of real patient experience. Without patient experience outcome data, this is an exercise that will have considerably more "unintended consequences" for patients. Patients with high impact/intractable pain can no longer afford to be the CDCs "unintended consequences".

We must face the fact that for many patients who live with high impact/intractable pain daily, the only effective medical solution may be opioids, and without substantive and equitable replacement, we must rely on patient education for those prescribed these medications and physician autonomy to prescribe the appropriate amount. Patients just want to get back to their lives in some shape or form. It is not enough to ask for a semblance of quality of life as we suffer excruciating pain. We need a return to physician autonomy to allow for patient-centered, individualized care, decisions based not in fear of regulatory attention, but in the best interest of individual patient's health. It would be naïve of the CDC to believe that even prescribing estimates published in a peer-reviewed

journal would not escape the sentiment of law, just as the expansion/revision of the guidelines. Please stop interfering in our medical care.

Thank you,
Stacey Turiello
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Stacey Turiello
about.me/stacey1

From: Kertesz, Stefan G
To: NCIPCBSC (CDC)
Subject: Submission of comment for today (July 22, 2020) BSC meeting on Acute / Chronic Pain
Date: Wednesday, July 22, 2020 1:28:57 PM

July 22, 2020

For CDC Board of Scientific Counselors

My name is Stefan Kertesz. I'm a professor of medicine, a federally funded addiction and health services scholar. I publish on opioids and hear about pain patients lost from care, and suicidal in relation to pain. I offer two ideas.

First, pain care is not opioid care. You know this, of course.

The challenge is that guidelines "about opioids" are inevitably seen as coning the question down to something like this: "Are opioids effective or not?" And, "Is non-pharmacologic treatment effective or not?" If treatment choices for lifelong pain were just like whether to give aspirin for a heart attack, A guideline committee's work would be simple.

But long-term pain is not a unitary condition. Patients have complex combinations of illnesses, resources, life histories, stigma, trauma, they live in communities, with or without resources.

All that complexity is factored out in randomized trials, by virtue of randomization, even if those factors matter when trying to make the right decision for a particular patient. If you craft a guideline, it should say that the right pain care must be individualized.

Second, any future CDC Opioid guideline **will not** be **just** a guideline, sadly.

Cautionary ideas about opioid duration and dose in 2016 were not implemented as guidelines.

The HHS Office of the Inspector General, at this time, quotes that 90 MME as the "dose to avoid". They report using that number to decide who their law enforcement partners should investigate. And "investigate" doesn't mean "look". It means seizing records, shutting down a practice and scattering the patients

In 2017 NCQA embraced a High Dose Opioid quality metric based on dose alone, despite entreaties from members of your group not to. That has incentivized stoppages. Papers in published in the last year show are often traumatic and dangerous, and allocated differentially to racial minorities.

I urge any future guideline demand a safe harbor to protect patients with complex illness and who might very well need opioids, even at high dose. I am glad to advise at any time.

Stefan G. Kertesz, MD, MSc
Professor, University of Alabama at Birmingham School of Medicine

Views are my own only, and do not represent any federal or state agency, including the US Department of Veterans Affairs

From:	Stu Shoger
To:	NCIPCBSC (CDC)
Subject:	Shoger 7/22 meeting comments
Date:	Monday, July 27, 2020 1:42:58 PM

To whom it may concern:

I am a care taker and spouse of a person with long term pain

There is a real crisis in this country in how the long term/ acute pain community in this country is being ignored, berated, under-served, and left to decide if ending their lives is the only alternative for relief.

The 2016 CDC recommendations, the HHS and the DEA/DOJ have swung the pendulum so far to the opposite side of the opiate/ addiction conversation that long term/ acute pain patients do not have access to the pain medications that they require just to function on a daily basis. In many cases this turns into severe depression and suicide. Doctors are being jailed for just taking care of their patients by prescribing what they believe is appropriate for that individual's needs. The government has cast a huge shadow over this community and no one cares. The Dr./patient relationship has been eroded to the point where the patient has no-where to turn for help.

Bringing this unbelievable American tragedy to light should inspire the American public, Congress and State governments to come to their senses and begin to understand that American citizens are suffering and dying from over-regulation and the Dr./patient relationship, without fear of retribution from our government, is a human right.

Thank you for the opportunity to express my concerns and I trust that you will consider that focused reforms for practical and essential pain care will be addressed.

Regards,

Steve Shoger
Fort Collins, CO 80521

From:	Stu Shoger
To:	NCIPCBSC (CDC)
Subject:	Shoger comments to 7/22/20 meeting
Date:	Tuesday, July 28, 2020 2:16:23 PM
Attachments:	image003.png

To whom it may concern:

I am a care taker and spouse of a person with long term pain

There is a real crisis in this country in how the long term/ acute pain community in this country is being ignored, berated, under-served, and left to decide if ending their lives is the only alternative for relief.

The 2016 CDC recommendations, the HHS and the DEA/DOJ have swung the pendulum so far to the opposite side of the opiate/ addiction conversation that long term/ acute pain patients do not have access to the pain medications that they require just to function on a daily basis. In many cases this turns into severe depression and suicide. Doctors are being jailed for just taking care of their patients by prescribing what they believe is appropriate for that individual's needs. The government has cast a huge shadow over this community and no one cares. The Dr./patient relationship has been eroded to the point where the patient has no-where to turn for help.

Bringing this unbelievable American tragedy to light should inspire the American public, Congress and State governments to come to their senses and begin to understand that American citizens are suffering and dying from over-regulation and the Dr./patient relationship, without fear of retribution from our government, is a human right.

Here are the points of contention that need to be justified:

- The CDC recommendations of 2016 are based on unsubstantiated research https://blog.usejournal.com/how-cdc-duped-the-nation-with-artificially-inflated-data-part-1-3f72251f360f

- The FDA is the governing body that dictates the prescribing requirements for opiates. There is no threshold.

- The AMA has provided a letter of June 16th, 2020 that amends the CDC recommendation to read that there should be no threshold for prescribing opiate medication in the doctor/ patient relationship.

> **Yet, the truth of the matter is that MME thresholds remain as hard policy by many health insurers, pharmacy chains, and PBMs.** The AMA strongly urges CDC to add language to the revised CDC Guideline urging those entities to rescind these policies given the absence of data to suggest a relationship between the arbitrary thresholds and improved patient outcomes—as well as the harms done to patients as a result of inappropriate tapering or denials of care. As such, the AMA recommends recasting this recommendation in its entirety:
>
> **Before starting long-term opioid therapy, and at periodic intervals thereafter, physicians should establish and review treatment goals with all patients, including shared goals for pain and function. Physicians should initiate opioid therapy with the lowest effective dose. Continued opioid therapy and/or dose escalation should occur only if there is clinically meaningful improvement or maintenance in treatment goals for pain and function that outweighs risks to patient safety. Hard thresholds should never be used.**

- Less than one percent of long term pain patients without a history of substance abuse problems become additcted during treatment.

Thank you for the opportunity to express my concerns and I trust that you will consider that focused reforms for practical and essential pain care will be addressed.

Stu Shoger
Project Manager/ Estimator

Phase 2 Company – WBE Certified
P.O. Box 1459
Fort Collins, CO 80522
970-482-7000 - Fort Collins
303-449-0101 - Denver Metro
970-231-2568 - Cell
stu.shoger@phase2co.com

From:	Gogu, Sujan
To:	Haegerich, Tamara M. (CDC/DDNID/NCIPC/DOP)
Cc:	Ragan, Kathleen (CDC/DDNID/NCIPC/DOP); NCIPCBSC (CDC); Dowell, Deborah (Debbie) (CDC/DDNID/NCIPC/OD); Opioids (CDC)
Subject:	CDC Opioid Task Force- Public Comments
Date:	Wednesday, July 22, 2020 1:42:07 PM
Attachments:	Sujan Gogu CV- VCOM-8.docx

Hello,

My name is Sujan Gogu and I am a triple board certified physician in family medicine, sports medicine, and pain management. I practice at Orthocare in Harlingen, Texas doing sports medicine and pain management. I was encouraged by the American Medical Society for Sports Medicine to apply for the workgroup formation which based on the workgroup formation I heard there is no representation by sports medicine or enough private practice physicians. The specialty of primary care sports medicine is a relatively new specialty and has excellent expertise in rehabilitation, pre-selection criteria for surgery, regenerative medicine (an emerging tool in treatments of patients), and managing pain while living an active lifestyle. **It is vital you consider a member of the specialty of sports medicine for the task force as we on an everyday basis get patients to return back to activity without the use of opioids. In addition, if you look at Major League Baseball and this past year a pitcher overdosed on opioids. In addition, several NFL players have and continue to use opioids during their playing days or after. Not having representation, from sports medicine will be a grave loss for the task force and our specialty as we are on the front lines treating athletes who sometimes want to revert to opioids for quick pain free life life thus unfortunately becoming addicted. I hope you reconsider your position and consider someone like myself who is triple boarded and has experience on many fronts based on my CV below.**

In addition, I wanted to make 2 statements:

1. We need to look at practices that are owned by private equity groups as they unfortunately are perpetuating this crisis. Currently the CDC has reccomendations that state to reassess if prescribed more than 50 MME thus many private practices are just keeping people chronically under 50 MME and doing UDS q1-3 months and profitting off the urine particullary on medicaid patients. We need to have more physicians with buprenorphine prescriber training and documentation in charts for patients for example with less than 50 MME were they offered specifically buprenorphine and counseling from a psychologist or psychiatrist. In the private sector the holistic care required for opioid use disorder is just not there and they are profiting off the urine which is unethical.

2. Some of the treatments such as Butrans patch, Belbuca, osteopathic manipulation, spinal cord stimulators, hyaluronic acid injections, ozone therapy, and regenerative medicine (starting to be accepted by insurances particularly Tricare) which I used in fellowship are very helpful combating pain with good outcomes but unfortunately insurance makes it so difficult to get with prior authorizations thus delaying care and patients insisting on same treatment or simply cost if the patient is a cash paying patient. I want these alternative options presented in the CDC guidelines thus the need for a **sports medicine physician part of the task force**.

Sujan Gogu, DO, ABFM
CAQ Sports Medicine

CAQ Pain Medicine

From: Terri Lewis
To: NCIPCBSC (CDC)
Date: Wednesday, July 22, 2020 5:07:59 PM

I am a clinical educator working within the field of rehabilitation and mental health. I train professionals working within disciplines of allied health and clinical practice. Design of measures, program evaluation, and systems engineering are a focus of my patient centered research in chronic pain. I am also the daughter of a parent with chronic pain; a sibling to a sister with chronic pain; and the parent of a young adult who has experienced chronic pain from the age of 12 years of age. In my role as a clinical educator, I review lots of patient records, which informs my education work with patient centered research and patient advocacy. It is in this capacity that I would like to express my concerns about data integrity.

The data that underlies our processes and informs our assumptions is very flawed and introduces errors into our analytics and assumptions across the system of care.

As we heard during this morning's work group report, the data we have is derived from *billable claims data*, which is based on encounters that are free of patient contextual factors. The metrics that underlie claims data are incorporated into electronic health records as algorithms. *In actual practice, billing claims data bears little or no relationship to treatment data*. Billing claims data is designed to service metrics bundled into system encounters and processes. It is not uncommon for billing data to overstate or understate the context in which care is delivered as it leans on processes. In this environment, chronic care data is often omitted from claims data for reasons associated with data design. Keep in mind that what gets measured gets managed. Patient context is largely unrepresented.

First, many physicians don't have a working understanding of how to implement all of the features of the ICD-10, diagnostics codes, HCPCs and encounter codes. Physicians work to coding contained in electronic health record algorithms – a check the box and copy, cut and paste so to speak. These are not constructed around multiple comorbidities.

Second, these datasets are designed around hospital, nursing home, emergency room (ER), hospital hospice care and home health care. It largely omits primary care settings from its design even though it is generalized to the community care setting. Patient reflected data is limited to measures of patient satisfaction reflecting encounter characteristics as captured in the Medicare Measures warehouse. This is neither results nor outcome data. One cannot ascertain whether the encounter actually materialized in the intended result from patient satisfaction data. One cannot measure chronicity with this data.

Third, DUR groupings are based on hospital billings, not community delivered care where the majority of service to persons with multiple chronic comorbidities (MCC) is provided. Rarely is there a single condition represented in comorbidity care, even though a single condition is represented in billing data – the one that gets paid for at the highest rate for the billable encounter.

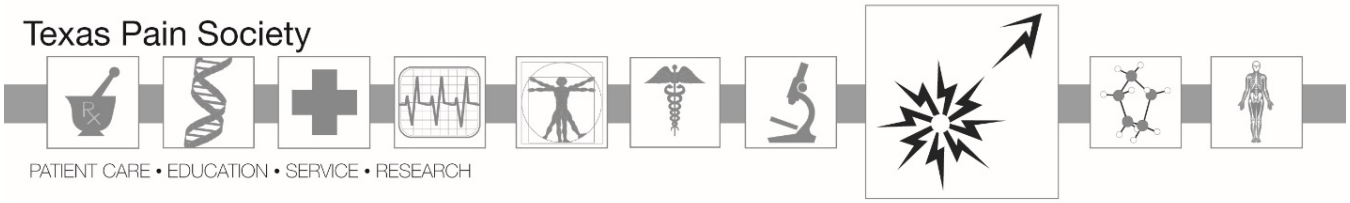
Fourth, the Chronic care codes that would help us to understand contextual factors that circulate around the development and progression of MCC over a lifetime of transitions are under-utilized for the chronic care population. In fact, many physicians have no idea that they are available for their use in either treatment planning or billing.

Fifth, these factors strategically separate claims data from treatment encounter data, bias our assumptions from the start, and cause us to ask the wrong questions about opioid use in the community prescribing context. Furthermore, these biases flow through insurance contracting evaluation five-star measures. The net effect is that the metrics we need to ascertain the state of the state for comorbidities context in which chronic pain care occurs is omitted.

The evaluation of data adequacy and integrity that underlies patient data incorporated into review of this important public health problem must become *part of the evidence review*.

Thankyou for the opportunity to comment.

Terri A Lewis Phd, NCC
Clinical Rehabilitation Educator
PO Box 146 Silver Point, TN 38582
Tal7291@yahoo.com
931-267-3532
615-649-4374



July 28, 2020

Via Electronic Submission NCIPCBSC@cdc.gov

Gwendolyn H. Cattledge, Ph.D., M.S.E.H
Deputy Associate Director for Science
CDC National Center for Injury Prevention and Control
4770 Buford Highway, NE, Mailstop S106–9
Atlanta, GA 30341

RE: Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC) Request for Comments – Opioid Workgroup

Dear Dr. Cattledge and members of the Committee,

Texas Pain Society (TPS) is a 501c6 nonprofit organization that represents over 350 pain specialists in Texas. Our vision is to improve the quality of life of patients in Texas who suffer from pain.

We at TPS applaud the CDC's opening of a docket request for stakeholder comments on acute and chronic pain management, and your desire to better understand stakeholders' values and preferences related to these important issues. We look forward to working collaboratively with you to ensure pain patients have access to the full spectrum of treatment options to reduce pain, opioid related harms, and improve function.

Pain care is at a critical crossroads in America and the need for updated guidelines and educational materials for patients and providers has never been greater. A 2019 Harris Poll of primary care physicians found increasing concerns about the challenge of appropriately treating pain patients and insufficient provider training in pain management -- with 83% of doctors reporting that the opioid crisis makes it harder to treat pain patients and 81% of doctors hesitant to accept new pain patients.

We respectfully request that the CDC incorporate the HHS Pain Management Best Practices Inter-Agency Task Force ("Task Force") recommendations, particularly section 2.4 Interventional Procedures. Our specialty organization endorse the Task Force's recommendations, as they provide an essential blueprint for balancing the need to effectively manage pain and reduce the opioid misuse crisis. We suggest that PCPs consider early referral to comprehensive pain specialists even prior to starting chronic opiate therapy if they are unable to provide the best practices outlined by the Task Force.

Our society recognizes that the millions of Americans currently living with chronic pain as a result of a myriad of diseases, conditions and serious injuries, are a vulnerable population of individuals who are often underserved and stigmatized for the very real problem of chronic pain. We would also recommend free or lower cost access to Naloxone for pain patients. While it has become easier to prescribe Naloxone, many patients still do not fill the prescription because the cost is prohibitive.

Updated CDC guidelines and pain educational materials would represent enormous progress towards effectively managing the complex and costly consequences of pain, including its impact on the opioid crisis. We collectively urge the CDC to meet with us to help you develop forward-thinking and appropriate recommendations.

We appreciate your time and consideration and look forward to discussing these concerns and ideas further with you. We may be contacted through Dr. Brian Bruel, President of Texas Pain Society.

Sincerely,

Brian Bruel, MD
Texas Pain Society President
On behalf of the entire Board of Directors

From:	Stacey Fields
To:	NCIPCBSC (CDC)
Date:	Tuesday, July 28, 2020 3:53:37 PM

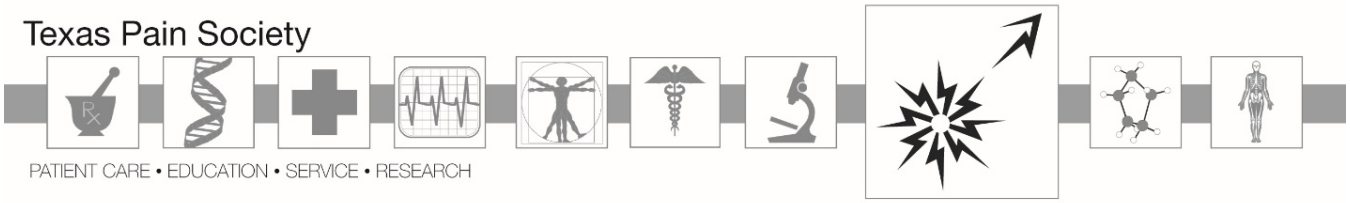
Hello

Patients have been telling you that what you are doing is harming them since this began in 2016. You say our feedback matters but clearly it does not. I run a group for chronic pancreatitis patients,(over 3800 members) we have lost 4 to suicide due to not having effective pain care. Others have turned to alcohol which WILL kill them since they have a bad pancreas. Still, others have turned to street drugs. You talk about sprains, lower back pain and fibromyalgia but nothing about MS, Pancreatitis, Lyme, CRPS and many other VERY painful conditions. I wish you could experience the pain these conditions cause then maybe you would understand just how much harm you are causing. For women on the task forces imagine being in labor 24/7, 365 days a year! The men involved should have to experience this as well, maybe with simulated pain for days on end. If you have never experienced any of these conditions you have absolutely no clue how painful they truly are. People have lost hope and many more are contemplating suicide to escape the pain you are forcing them to live in. You have said this is about addiction yet the states (all of whom received millions from the gov) are cutting funding to addiction services. The CDC has already admitted they skewed the numbers and the AMA has spoke out and told you you are wrong in what you are doing. What is it going to take to get any of you to have some ethics and stop this madness? -- We no longer go to the E.R. when we clearly need to, this almost cost me my life and if I had gone when I should have they surely would have caught the cancer sooner, stage 3C colon cancer! This is the most unethical discriminating policy of my lifetime and it horrifies me to think my children and grandchildren will be forced to live in horrific pain at the hands of the very people trained to help us. Many of us will no longer have any medical procedures because we are afraid and this will flow into the public that are not ill as soon as they get mistreated by the medical people whose hands you have tied. Maybe then we will see protests over this that get out of hand and cause the sort of damage we are seeing right now. Colonoscopies without anaesthesia, no pain care after a double mastectomy or no pain care for cancer patients, how can you justify this? All of this WILL cause more death and despair all at your hands. We can only hope that someone will come to their senses soon. Pain IS and still should be the 5th vital sign as it is a sign that something is WRONG in our bodies. People will stop getting proper medical care and the medical industry will suffer big money losses. We are tired of suffering and will not support those who don't support us. I know this is falling on deaf ears but I need to say it again even if no one is listening! You have also thrown science out the window all on the word of a self-appointed opioid expert who knows NOTHING about these diseases or the pain they cause but clearly that doesn't matter either! As I said before this is the worst policy of my lifetime and I do not understand how you people can do this to your fellow Americans who are struggling to live and have ANY quality of life.u must know the increase in suicides is directly related to people not having proper pain control but hey that doesn't matter either does it? Thousands have died at YOUR hands! Have you all forgotten the days of Waverly and other institutions where psychiatrist abused patients horribly? This is another rendition of those days of horrific suffering and death.

--

Stacey Fields
The National Chronic Pancreatitis Support Network

 Pancreatitis....Pick up the fight!



July 28, 2020

Via Electronic Submission NCIPCBSC@cdc.gov

Gwendolyn H. Cattledge, Ph.D., M.S.E.H
Deputy Associate Director for Science
CDC National Center for Injury Prevention and Control
4770 Buford Highway, NE, Mailstop S106–9
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We appreciate your time and consideration and look forward to discussing these concerns and ideas further with you. We may be contacted through Dr. Brian Bruel, President of Texas Pain Society.

Sincerely,

Brian Bruel, MD
Texas Pain Society President
On behalf of the entire Board of Directors

From: Tricia Moore
To: NCIPCBSC (CDC)
Subject: Pain control
Date: Thursday, July 23, 2020 4:50:40 PM

I am writing this today as to the cdc on pain management control. I am a patient with multiple autoimmune diseases such as systemic lupus and others. It's a daily battle trying to do even the smallest tasks without pain meds. I have been in pain management for many years and have had my dosage cut so much that I barely function anymore I can hardly shower much less do household chores. I've been treated as a junkie or just treated like my pain doesn't matter. Dr.'s are afraid to give me meds that can help because they are afraid the dea will say they write to high of scripts. It's insane to think that the dea can control my daily life of function. Please help us that's suffering on a daily basis. Many people have committed suicide because they can't take the pain anymore. It's wrong! Thank you for your time.

Suffering patients,
Tricia Moore

From:	tgunnard
To:	NCIPCBSC (CDC)
Subject:	Life of a chronic pain patient
Date:	Tuesday, July 21, 2020 12:12:31 PM

Dear Sirs and Madams,

I am a 58 year old disabled RN in SW Florida. I have been suffering from chronic intractable pain since my early 20's due to chronic autoimmune disorders such as Lupus, Rheumatoid Arthritis, Spinal Stenosis and Sjogren's disease. I have been on opioid pain management, steroids, steroid injections, have had over 60 surgeries, accupuncture, massage therapy, PT and many other treatments. I have my knees, hips, back and neck regularly injected to help with the pain.

I am not sure if you are aware of the side effects of steroids but there are many unpleasant ones. One that bothers me the most is the incredibly disfiguring bruising it causes, as well as Buffalo hump, Moonface and what it does to your insides. I look absolutely terrible!

I have 35 years experience in Nursing, mostly in Hospice care and children. I haven't been able to work regularly due to the amount of pain I suffer and recoveries from all the surgeries I have had.

About 7 years ago, my doctor increased my opioid to Fentanyl patch 125 mcg's, and a short acting opioid such as oxycodone as needed. At that time, I felt so little pain I was able to work full-time with over-time, and even volunteered at my local Sheriff's office in Crime Prevention. I was able to get off disability for a while and enjoyed life immensely!

Fast forward to 4 years ago...

My opioids were cut in half. I had to quit the job I loved more than anything, stop volunteering and spend life mostly in bed or on the couch because of the pain. I have lost my identity and wish that my life would end sooner rather than later.

This is No Way To Live! I am so depressed and feel worthless as a human being, relying on my 27 year old daughter and 78 year old mother to help care for me and my home. I should be taking care of THEM!

My pain management physician checks my opioid levels monthly to make sure I am taking it correctly and obviously not selling it. My medications are locked up in a safe. I am now on 75 mcg's of fentanyl patch and my physician is trying to decrease it to 50 mcg's which the DEA prefers because I am above some score they have that prescribing physicians have to stay under. I am even told Medicare is likely not to cover the current dose of opioids I am on and that my pharmacy may stop filling my medication at any time. This stress does not help my current outlook on my future.

During your meeting, I feel a representative of the DEA should attend, as well as a congressman from each state. We need to get the CDC's new Best Practices report through to congress so chronic pain patients can live the life that everyone else is living, productively and comfortably. Physicians only follow the DEA recommendations on opioids, not the CDC's.

I am 58 years old and had many years left as an RN. I made enough money to live comfortably. Now poverty has also become part of my life and my daughter has to support me. I am pouring tears as I write this, feeling as though I will spend the rest of my days with pain of an 8 or 10.

Thank you for reading this. I pray something good comes from your meeting. God Bless.

Sincerely,

Trish Gunnard
Punta Gorda, FL

Sent from my Verizon, Samsung Galaxy smartphone

From:	bock1
To:	NCIPCBSC (CDC)
Subject:	Narcotics for chronic pain
Date:	Wednesday, July 22, 2020 9:03:40 AM

Please, I am begging you to read this through.

I am 52 years old with a large amount if health problems inclucing:

1 low back surgery
2 cervical surgeries with a titanium cage
1 shoulder surgery
2 knee surgeries and needing replacements
Stage 4 nonalcohol liver cirrhosis
Diabetes
Rheumatoid arthritis
Varicose veins
Migraines so bad I'm on social security
Brittle bones. Broke 3 in last 12 months

I suffer every second of the day. If my liver isn't working the best that day, it doesn't get the pain medication through my body. I had been on the same high dose of medicine that my pain doctor prescribed. He was an anesthesiologist at Mayo Clinic in Rochester at the time.

I was FINALLY able to have a productive quality if life. I was able to do foster care to dozens of needy children who wouldn't have gotten out if a mental hospital if it weren't for being able to live in the home of qualified persons with college degree us psychology/sociology. The sheer joy to be able to give back to society despite my many health problems that kept me from the 9 to 5. I could LIVE again.

Then somewhere this opioid crisis hit and my life plummeted again. Trust me, I am in board for keeping drugs out if the wrong hands. I worked as a Rule 25 assessor and a chemical dependency social worker. I know first hand all to well how horrible this problem is. I have worked tirelessly helping others.

But now, in my life, I have gone back to sitting on the couch typing you this email because I am in so much pain I can't move. My medications have been tapered back so far that I can no longer have a favorable quality of life for myself and immediate family let alone talk about self-actualization any more. My provider told me again two days ago that I have to be tapered further because they fear getting in trouble with the "powers that be" and losing their credentials.

I wish I could wave a magic wand and make effective pain control medication nonaddictive and have no euphoric feelings so people wouldn't seek them for recreational use or self medicating mental health issues

I wish I could wave a wand and take away all the pain in the world

I wish I could wave a wand and immediately make some middle ground where a person who is under the direct care of a qualified doctor or pain center where they are seen at least bimonthly and are given blood work to be sure they are appropriately following the rules are exonerated from these limits and controls and the provider can be free from fear of being in trouble for giving the appropriate amount of medication appropriate to that patient's needs

Persons in Chronic Pain need those higher levels if medication just to function. We don't look for a pain free life. We look for a tolerable level where life can have some meaning and joy

I beg you.....

My husband also is a patient and suffers similar repercussions due to these same issues.

We would love to come speak to you in person about our lives on both sides of the fence . We need to find a way to help those in need while protecting those also in need if those same meds to just make it to the breakfast table

Wendy & LuVerne Bock
1117 Plainview Lane
Albert Lea, MN 56007
Bock1@charter.net
507-391-1230

Closing Comments / Adjournment

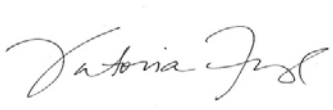
Dr. Frye thanked the members of the public and callers who offered their commentary. These will be taken into consideration by the CDC. The BSC will be discussing what they have heard and will provide feedback and council, as is their charge. She apologized for not recognizing the disastrously negative impact of suicides at the beginning of our meeting and requested that they take a moment of silence to recognize those people who have lost their lives to suicide. Suicides have increased significantly in the last several years. The next BSC meeting will be in August 2020. The exact date and time will be announced.

Dr. Greenspan reminded BSC members and *ex officios* to send an email to confirm their presence to ncipcbsc@cdc.gov. She expressed her appreciation for everyone's participation in the meeting.

With no announcements made, further business raised, or questions/comments posed, **Dr. Frye** thanked everyone for their attendance and participation and officially adjourned the Thirty-Third meeting of the NCIPC BSC at 1:30 PM.

Certification

I hereby certify that to the best of my knowledge, the foregoing minutes of the July 22, 2020 NCIPC BSC meeting are accurate and complete:



10/10/2020
Date

Victoria Frye, DrPh, MPH
Chairperson, NCIPC BSC

Attachment A: Meeting Attendance

Donna H. Barnes, Ph.D.
Associate Professor
Department of Psychiatry and Behavior Sciences
Howard University

Roger Chou, M.D.
Professor of Medicine
Oregon Health and Science University
Departments of Medicine, Medical Informatics and Clinical Epidemiology

Kermit Crawford, Ph.D
Associate Professor in Psychiatry
Department of Psychiatry Psychology
School of Medicine
Boston University

Chinazo Cunningham, M.D., M.S.
Division of General Internal Medicine
Albert Einstein College of Medicine
Montefiore Medical Center

Frank Floyd, M.D., F.A.C.P.
Medical Director
United Health Service Medical Group

Frank A. Franklin, II, Ph.D., J.D., M.P.H.
Principal Epidemiologist and Director
Community Epidemiology Services
Multnomah County Health Department

Victoria Frye, Ph.D.
Associate Medical Professor
School of Medicine
City University of New York

Elizabeth Habermann, Ph..D
Professor
Department of Health Services Research
Mayo Clinic College of Medicine and Science

James Hedlund, Ph.D.
Principal
Highway Safety North

Todd Herrenkohl, Ph.D.
Professor and Co-Director 3DL Partnership
School of Social Work
University of Washington

Mark S. Kaplan, Dr.P.H.
Professor of Social Welfare
Department of Social Welfare
Luskin School of Public Affairs

Karen D. Liller, Ph.D.
Professor
Department of Community and Family Health
University of South Florida,
College of Public Health

Christina A. Porucznik, Ph.D., MSPH
Associate Professor
Department of Family and Preventive Medicine
University of Utah

David C. Schwebel, Ph.D.
Associate Dean for Research in the Sciences
University of Alabama at Birmingham

Daniel J. Whitaker, Ph.D.
Professor, Director
Health Promotion & Behavior
Georgia State University

Ex-Officio

Melissa Brodowski, Ph.D., M.S.W., M.P.H.
Senior Policy Analyst
Administration for Children and Families

Mindy Chai, J.D., Ph.D.
Health Science Policy Analyst
Science Policy and Evaluation Branch
National Institutes of Health
National Institute of Mental Health

Wilson Compton, M.D., M.P.H.
Deputy Director
National Institute on Drug Abuse
National Institutes of Health

Holly Hedegaard, M.D., M.S.P.H.
Senior Service Fellow
National Center for Health Statistics
Centers for Disease Control and Prevention

Lyndon Joseph, Ph.D.
Health Scientist Administrator
National Institute on Aging
National Institutes of Health

Valerie Maholmes, Ph.D., CAS
Chief, Pediatric Trauma and Critical Illness Branch
National Institutes on Health
Eunice Kennedy Shiver National Institute of Child Health and Human Development

Constantinos Miskis, J.D.
Bi-Regional Administrator
Administration on Community Living,
Administration on Aging

RADM Kelly Taylor, M.P.H.
Director, Environmental Health and Injury Prevention
Indian Health Service

Captain Josefine Haynes-Battle, MSV, BSN, RN
CAPT, United State Public Heath Service
Director, SAMHSA/CSAP/Division of System Development

CDC Attendees

Victor Cabada, M.P.H.
Gwendolyn Cattledge, Ph.D.,, MSEH, FACE, CHM
Casey Chosewood, Ph.D.
Melvin Crum, Ph.D.
Linda Dahlberg, Ph.D.
Rosalyn Lee, Ph.D.
Deborah Dowell, M.D., M.P.H.
Arlene Greenspan, Dr.P.H., M.P.H.
Debra Houry, M.D., M.P.H
Chris Jones, Ph.D.
Tonia Lindley
Amy Peeples, M.P.H.
Tom Simon, Ph.D.
Mildred Williams-Johnson, Ph.D., D.A.B.T.

Public Attendees
Carl Beck
On- Par Productions

Natalie Green
On-Par Productions

Antwan Jones
On-Par Productions

Attachment B: Acronyms Used in this Document

Acronym	Expansion
AAMC	Association of American Medical Colleges
ACEs	Adverse Childhood Experiences
ACR	American College of Radiology
ADL	Activities of Daily Living
ADS	Associate Director for Science
AEs	Adverse Events
AHRQ	Agency for Healthcare Research and Quality
ALD	Academy of Laser Dentistry
AMA	American Medical Association
BSC	Board of Scientific Counselors
BUP	Buprenorphine
CADCA	Community Anti-Drug Coalitions of America
CDC	Centers for Disease Control and Prevention
CE	Continuing Education
CIAAG	Chronic Illness Advocacy & Awareness Group, Inc.
CME	Continuing Medical Education
CMS	Medicare and Medicaid Services
COI	Conflict of Interest
CRPS	Complex Regional Pain Syndrome
CSA	Child Sexual Abuse
CSELS	Center for Surveillance, Epidemiology, and Laboratory Services
CV	Curricula Vitae
DC	District of Columbia
DFC	Drug-Free Communities Support Program
DFCB	Drug-Free Communities Branch
DFO	Designated Federal Official
DOP	Division of Overdose Prevention
DSM-V	Diagnostic and Statistical Manual of Mental Disorders-V
ED	Emergency Department
FACA	Federal Advisory Committee Act
FASTER	Firearm Injury Surveillance Through Emergency Rooms
FDA	Food and Drug Administration
FRN	*Federal Register Notice*
FY	Fiscal Year
Georgia Tech	Georgia Institute of Technology
HCP	Healthcare Providers
HHS	(Department) Health and Human Services
IASP	*Journal of the International Association for the Study of Pain*
ID	Identification
IPV	Intimate Partner Violence
JHU	Johns Hopkins University
JLME	*Journal of Law, Medicine & Ethics*
LTOT	Long-Term Opioid Therapy
MASCC	Multinational Association for Support of Care in Cancer
MAT	Medication Assisted Treatment
MME	Morphine Milligram Equivalents

Acronym	Expansion
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NCHS	National Center for Health Statistics
NCIPC	National Center for Injury Prevention and Control
NVDRS	National Violent Death Reporting System
OD2A	Overdose Data to Action
OI	Office of Informatics
OLDW	OptumLabs Data Warehouse
ONDCP	Office of National Drug Control Policy
OPE WG	Opioid Prescribing Estimates Workgroup
OSI	Office of Strategy and Innovation
OUD	Opioid Use Disorder
OWG	Opioid Workgroup
PACE	Preventing Adverse Childhood Experiences
PBM	Photobiomodulation
PDMP	Prescription Drug Monitoring Program
PROP	Physicians for Responsible Opioid Prescribing
RCT	Randomized Clinical Trials
RDS	Reflex Sympathetic Dystrophy
RN	Registered Nurse
SAMHSA	Substance Abuse and Mental Health Services Administration
SBI	Strategic Business Initiative Unit
SCD	Sickle Cell Disease
SCS	Spinal Cord Stimulator
SUD	Substance Use Disorder
TENS	Transcutaneous Electrical Nerve Stimulation
US	United States
USPHS	United States Public Health Service
WG	Workgroup
WIP	World Institute of Pain