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"The Voice of Interventional Pain Management"

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March 30, 2022

National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway NE, Mailstop S106-9
Atlanta, GA 30341

Re: Docket No. CDC-2022-0024 - Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids

On behalf of American Society of Interventional Pain Physicians (ASIPP), Society of Interventional Pain Management Surgery Centers (SIPMS), and 49 state societies of interventional pain physicians, we thank you for updating 2016 Centers for Disease Control and Prevention (CDC) guidelines. While the 2022 guideline is a significant improvement over the 2016 guideline, it still needs significant revision, including revisions of the U.S. Department of Health & Human Services (HHS) Best Practice Guidelines developed by Congressional mandate through the Comprehensive Addiction and Recovery Act (CARA) Act. Our major concerns are based on our experience with the 2016 guidelines, which have had deleterious effects in managing chronic pain patients and have propelled the fourth wave of epidemic with unforeseen illicit opioid drug deaths. The repercussions of the guidelines have also significantly affected interventional pain management. The majority of the problems are the result of Dr. Roger Chou's influence. It is rather surprising that the CDC has sponsored studies headed by Dr. Chou, while also making him one of the principal authors of the guidelines. Unfortunately, he was involved in developing the interventional pain management guidelines (for which he has no expertise), as well as the opioid guidelines, along with evidence synthesis. Thus far, no information has been provided in reference to the numerous conflicts of interest that Dr. Chou's multiple positions pose. Consequently, we request the following to be considered and incorporated into the upcoming guidelines:

1. Interventional techniques as defined by MedPAC including epidural and facet joint interventions, spinal cord stimulation, intrathecal infusion systems, minimally invasive endoscopic surgery, interspinous prosthesis, posterior lateral fusion with arthrodesis, vertebral augmentation procedures, sacroiliac joint interventions, and other techniques, are safe with extensive evidence of clinical and cost effectiveness with improvement in quality of life, thus reducing dependence on opioids, leading to attenuation of fourth wave of illicit drug epidemic.
2. The CDC guidelines must eliminate mission creep of providing standard of care with only restricted opioid use without multiple interventional techniques as recommended by HHS Best Practice Report.
3. As evidenced by extensive literature, excluding the literature by Chou et al, interventional pain management strategies, in conjunction with other modalities, have shown to be effective as evidenced by HHS Best Practices Report.

As you well know in 2011, Roger Chou, as part of a group including Von Korff and Calodney, co-authored an article (1) with the announcement of the creation of Physicians for Responsible Opioid Prescribing (PROP), which has planned to entirely eliminate opioid therapy. Furthermore, they also noted that the guidelines for long-term opioid therapy should not be developed solely within the field of pain medicine. Unfortunately, the CDC has not participated in the Best Practice Task Force guidelines which involved physicians from both clinical and academic settings. Rather, the CDC has chosen to involve only a few select people and adopt their literature for the writing of the CDC guidelines. As a result, despite any alleged changes, it appears PROP continues to have a substantial influence on guideline preparation.

Dr. Chou also wrote Pain Management Injection Therapies for Low Back Pain (2) Technology Assessment Report from the Agency for Healthcare Research and Quality (AHRQ), the cost of which, not surprisingly, is unavailable to the public. They followed the AHRQ Technology Assessment Report with a publication in *Annals of Internal Medicine* (3) concluding that epidural steroid injections do not work. Manchikanti et al (4) have reported multiple concerns regarding that article and the entire guideline process spearheaded by Dr. Chou and others. The major error in their assessment of epidural injections and other types of therapies is that Dr. Chou, and others with the same philosophy, have chosen to convert all active-controlled trials utilizing local anesthetic alone or local anesthetic with steroids into placebo controls, whereby they consider local anesthetic as a placebo despite extensive literature to the contrary. Multiple studies have shown the therapeutic effects of sodium chloride solution injected into the epidural space (5). In the same vein, multiple systematic reviews have shown the effectiveness of local anesthetics with or without steroids (6-11). Shanthanna et al (12) clearly demonstrated that steroids may not only have short-term effects but may also be associated with significant risk. Manchikanti et al (4) published a comparative systematic review of Chou et al (3) identifying numerous deficiencies in their review as described above. As stated, these deficiencies included conversion of active controls into placebo controls, improper methodological assessment, and the integration of multiple disputable studies into their review leading to faulty conclusions. The authors purported that epidural lidocaine alone or lidocaine in conjunction with steroids were only minimally effective and that any benefits were not sustained. Because Chou and others with similar philosophy, served as experts in the development of local coverage determinations (LCDs), they recommended against any interventional techniques. Consequently, utilization of interventional techniques has declined significantly from 2010 to 2019 at an annual rate of 2.5%, and with the superimposition of COVID-19, they declined 18.7% (Fig. 1). Numerous authors have refuted Chou's findings, demonstrating the effectiveness of interventional techniques, including epidural injections, facet joint interventions, percutaneous adhesiolysis, radiofrequency neurotomy procedures, vertebral augmentation procedures, and neuromodulation techniques and have shown that these procedures improve the quality of life in a significant proportion of patients with cost utility.

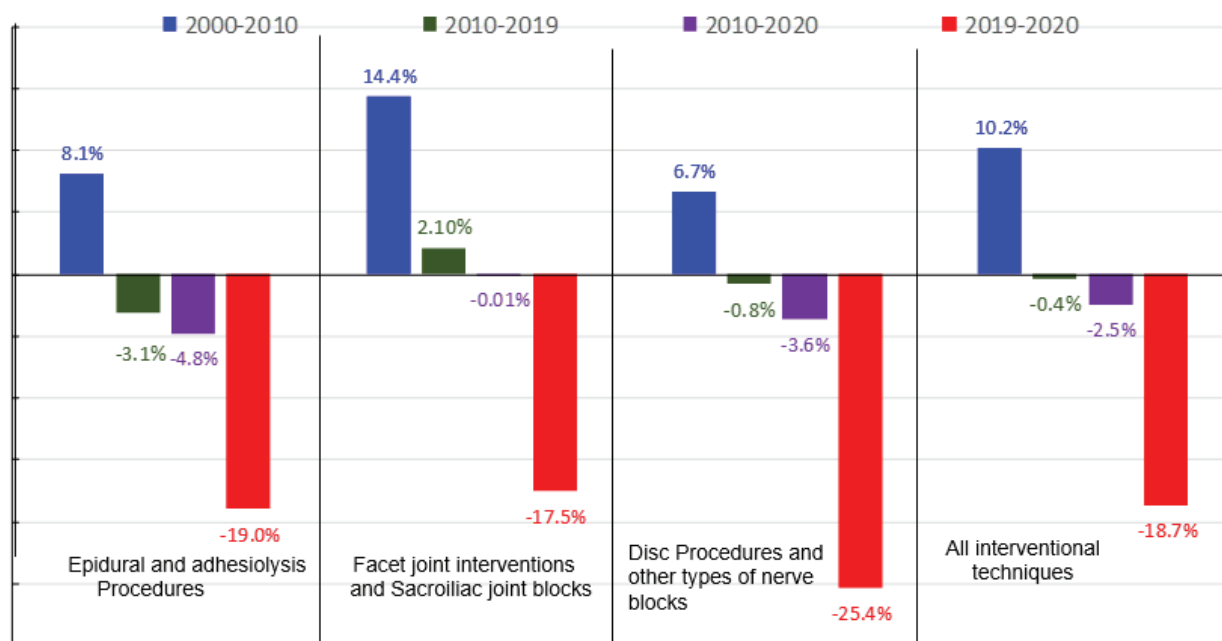
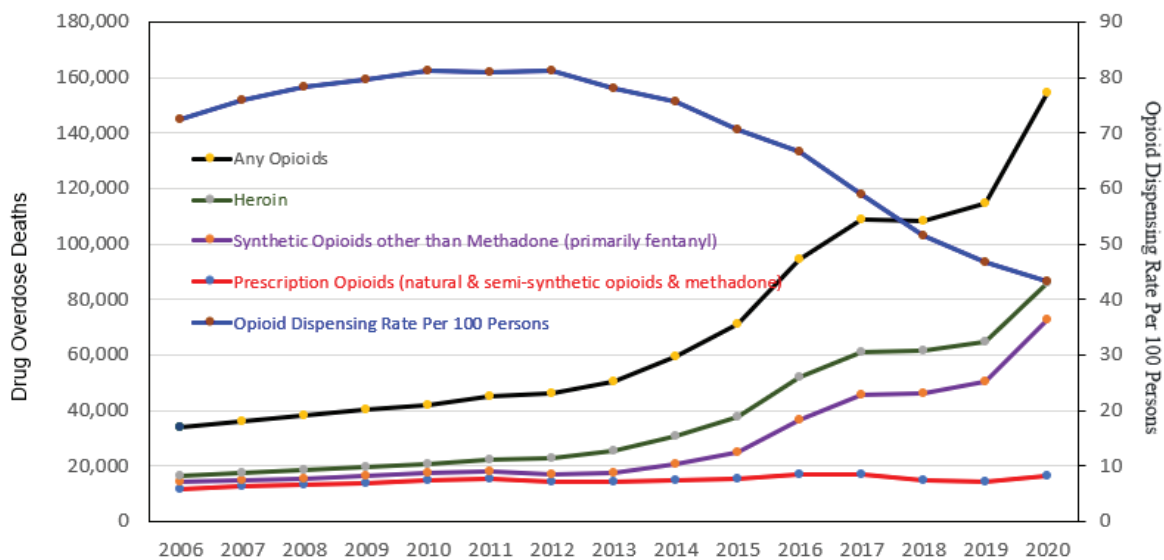


Fig 1. Comparative analysis of rate (per 100,000 Medicare recipients) of usage patterns for epidural and adhesiolysis procedures, facet joint interventions and sacroiliac joint blocks, disc procedures and other types of nerve blocks, all interventional techniques (geometric average annual change in rates).

Consequently, we are requesting that the CDC utilize objective, fact-based and impartial guidelines and systematic reviews (13-20), rather than biased and opinion-based guidelines. Incorporating evidence-based guidelines, founded on the extensive literature available for interventional pain management techniques (16-21), and based on multiple systematic reviews summarizing the evidence from randomized controlled trials demonstrate that interventional techniques including epidural injections, percutaneous adhesiolysis, facet joint interventions such as radiofrequency

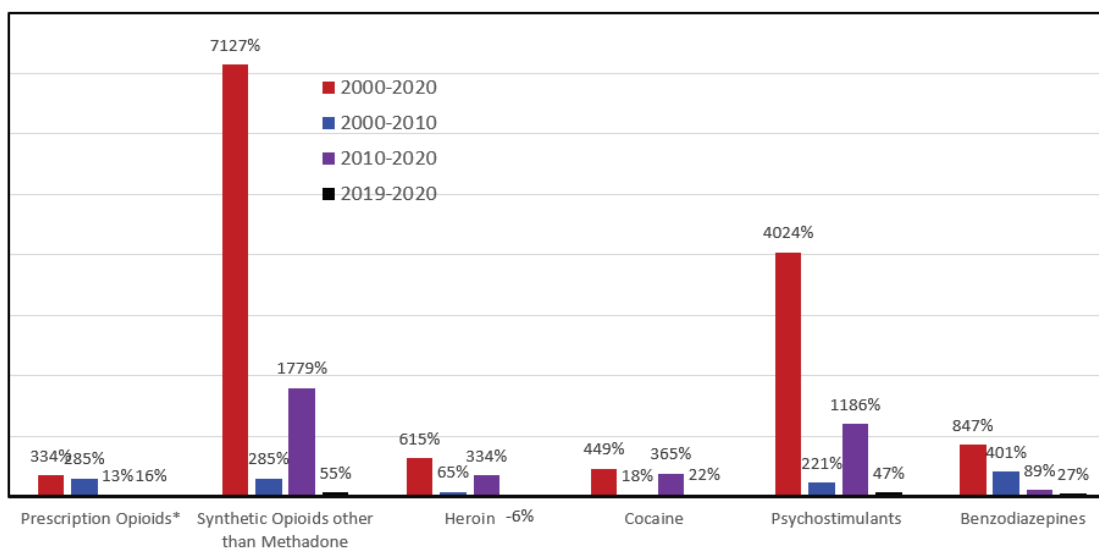
neurotomy, sacroiliac joint injections and neurotomy, vertebral augmentation procedures, and spinal cord stimulation, as well as intrathecal infusion systems have been shown to have Level I to III evidence with strong to moderate recommendations when performed appropriately according to LCDs, medical policies, and published literature (13-20).

Based on current publications and recommendations, it appears that the CDC remains nescient of the opioid paradox and does not recognize that with the CDC recommended reduction in the number and frequency of opioid prescriptions, as well as MME, as shown in Fig. 2 (21), there has been an increase in the use of non-prescribed/diverted opioids, synthetic opioids and heroin. Figures 3 and 4 show quantification of opioid deaths from 2000 to 2020 and four waves of the rising opioid overdose deaths, and, finally, Fig. 5 shows the national drug induced overdose deaths from a variety of opioids. The CDC should be very familiar with this data since most of the data is adapted from CDC publications.



Source: <https://www.cdc.gov/nchs/products/databriefs/db428.htm>
<https://www.cdc.gov/drugoverdose/rxrate-maps/index.html>
 Accessed on 1/25/2022

Fig. 2. *The opioid paradox. Opioid prescriptions are declining while opioid overdose deaths are increasing.*



	2000	2010	2017	2018	2019	2020	Change			
							2000-2020	2000-2010	2010-2020	2019-2020
Prescription Opioids (natural & semi-synthetic opioids & methadone)	3,785	14,583	17,029	14,975	14,139	16,416	334%	285%	13%	16%
Synthetic Opioids other than Methadone (primarily fentanyl)	782	3,007	28,466	31,335	36,359	56,516	7127%	285%	1779%	55%
Heroin	1,842	3,036	15,482	14,996	14,019	13,165	615%	65%	334%	-6%
Cocaine	3,544	4,183	13,942	14,666	15,883	19,447	449%	18%	365%	22%
Psychostimulants	578	1,854	10,333	12,676	16,167	23,837	4024%	221%	1186%	47%
Benzodiazepines	1,298	6,497	11,537	10,724	9,711	12,290	847%	401%	89%	27%

Fig. 3. Quantification of opioid deaths 2000-2020.

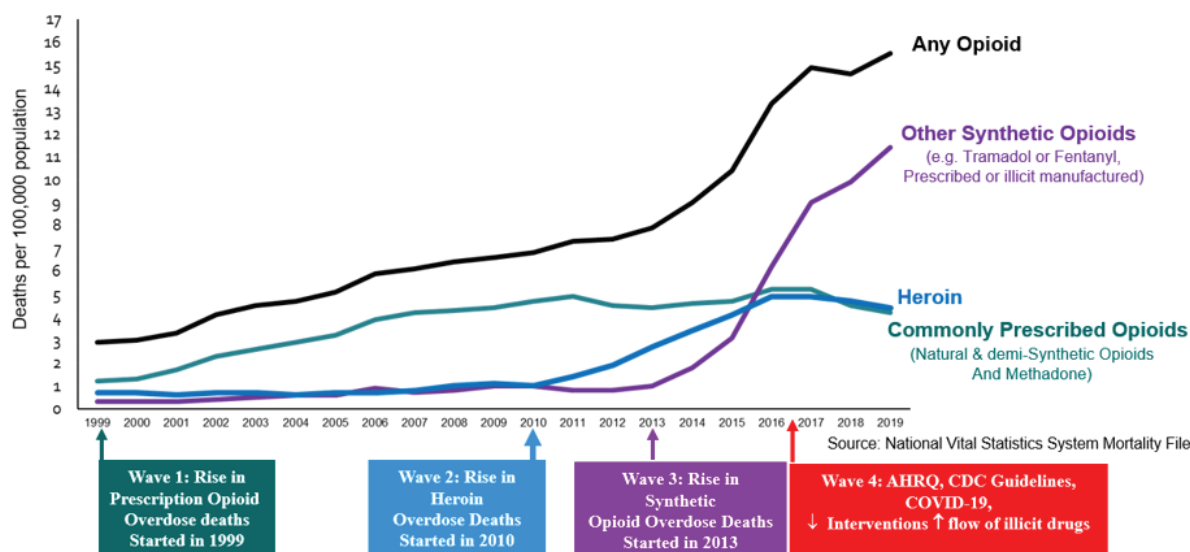
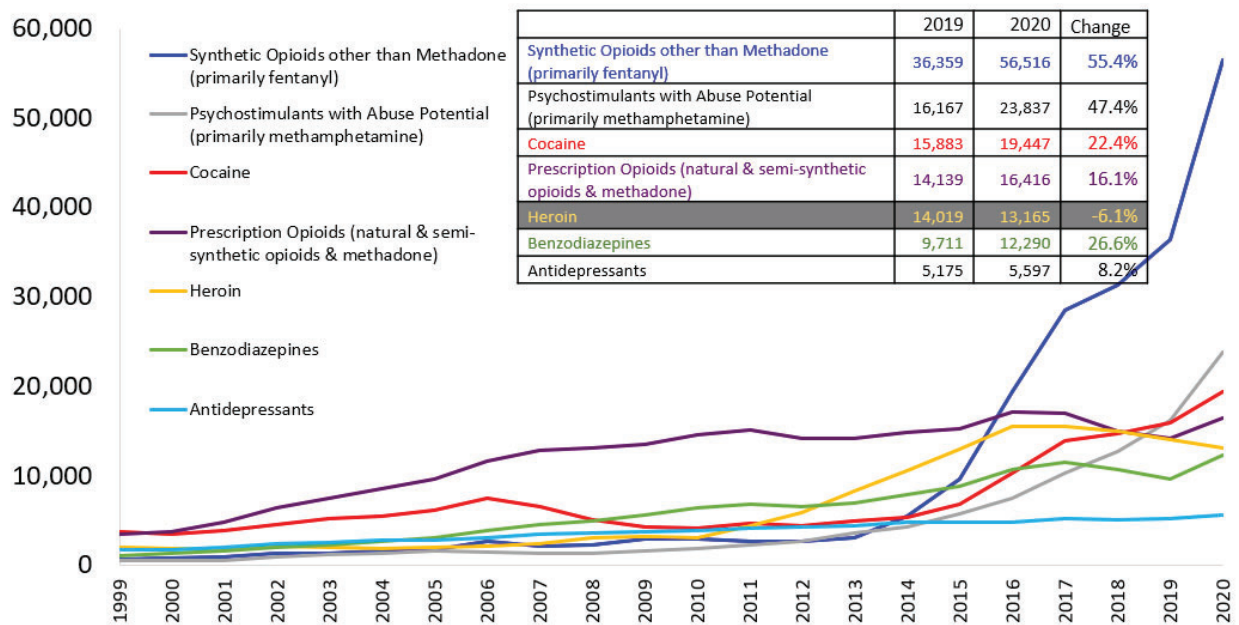


Fig. 4. Four waves of the rise of opioid overdose deaths.



*Includes deaths with underlying causes of unintentional drug poisoning (X40–X44), suicide drug poisoning (X60–X64), homicide drug poisoning (X85), or drug poisoning of undetermined intent (Y10–Y14), as coded in the International Classification of Diseases, 10th Revision. Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999–2020 on CDC WONDER Online Database, released 12/2021.

Fig. 5. National drug-involved overdose deaths*, number among all ages, 1999-2020.

These deleterious effects are due to rapid opioid dosage tapering and dose reductions, which has also led to a significant increase in deaths and appears to be responsible for the exploding fourth wave (15).

Alarmingly, CDC guidelines that should have been received as clinical recommendations, are being indiscriminately imposed as regulations.

The opioid overdose waves of the past three decades have differed in their etiologies. Wave one was associated with prescription opioid overdose deaths. Wave two was primarily the result of the rise in heroin and overdose deaths from 1999 to 2013. Wave three was associated with a rise in synthetic opioid overdose deaths.

Wave four appears to be a perfect storm resulting from a confluence of factors including the CDC opioid prescribing guidelines, the COVID pandemic, the increased availability of illicit synthetic opioids and the reduction of access to interventional techniques, all or any of which lead patients to seek remedies on their own. Sadly, the number of deaths resulting from wave four continue to escalate. ASIPP and its members are alarmed by the relentless rise of wave four and we beseech the CDC to join us in the fight for the lives of our patients.

ASIPP is a not-for-profit professional organization founded in 1998 now comprising over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States. ASIPP is comprised of 49 state societies of Interventional Pain Physicians, including Puerto Rico and the affiliated Texas Pain Society.

If you have any further questions, please feel free to contact us. Again, thank you for considering our comments on behalf of American Society of Interventional Pain Physicians (ASIPP).

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