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National Council on Independent Living

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Theo Braddy
Executive Director

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Dear Senators and Representatives,

We write this letter on behalf of the undersigned disability rights organizations. As organizations that advocate for the civil and human rights of people with disabilities, we remain highly concerned about access to appropriate treatment for people with substance use disorders and people with serious pain. We write to update our letter from January 2024, with concerns from the disability community regarding new bills including the SUPPORT for Patients and Communities Reauthorization Act.

We greatly appreciate Congress' work to address opioid addiction and overdose, including expanded access to treatment for substance use disorder, OAT (opioid agonist therapy), and overdose reversal medication. We especially applaud the easing of requirements for medication-assisted treatment (MAT) included in the Consolidated Appropriations Act of 2023. We are, however, alarmed that as efforts to address opioid addiction have moved forward, the needs of people with serious pain continue to be addressed inappropriately or left out entirely.

We advocate for access to the full spectrum of treatments for pain, along with research to develop new treatments. Indeed, it is often a combination of therapies that allows individuals to most effectively manage their pain. Yet in recent years, many policies have continued to erect barriers that increasingly leave people with disabilities unable to access pain medication or healthcare altogether. People are being forcibly or abruptly tapered off their medications in dangerous ways – often with devastating results, such as increased suffering, loss of function, overdose and suicide. Reports confirm that clinicians are forcibly reducing dosage or stopping opioid prescribing in patients they believe benefit from the medication, out of fear of oversight.[1]

Observing these harms, the Centers for Disease Control (CDC),[2] the Department of Health and Human Services (HHS),[3] and the Food and Drug Administration (FDA),[4] issued safety alerts in 2019 warning against misapplication of the 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain*. Nevertheless, federal bills introduced in previous sessions contained precisely the type of limits the CDC and others have come out against.

On November 3, 2022, the CDC released an updated 2022 *Clinical Practice Guideline for Prescribing Opioids for Pain*, clearly warning that policies creating inflexible limits on prescribed opioids contravene the *Guideline* and incur serious risks to patient safety.[5] Day and dose limits have now been removed from the *CDC Guideline's* primary recommendations.[6]

(202) 207-0334 (Voice)
(202) 207-0341 (Fax)
(844) 778-7961 (Toll-Free)

PO Box 31260
Washington, DC 20030
Email: ncil@ncil.org

Policies to limit the prescribing of controlled substances have failed to make a measurable difference in today's overdose crisis. Despite opioid prescribing falling to low (per capita) levels last seen in 1993,[7] data from the CDC shows deaths related to illicit fentanyl have spiked by more than 1000% between 2013-2021, while deaths related to prescribed opioids stayed roughly constant.[8] Recent studies have even suggested that laws limiting prescribing may, inadvertently, result in more overdose deaths.[9]

Discontinuation of long-term opioid therapy is associated with increased risk of overdose and suicide, as well as increased risk of death from all causes, even years later.[10] [11] [12] [13] Tapering often occurs too abruptly – sometimes within 24 hours – often resulting in hospitalization or emergency care.[14] One study in Colorado found that simply destabilizing dosage resulted in a three-fold increased risk for opioid overdose.[15]

Very recent studies suggest that dose tapering, even absent opioid cessation, resulted in heightened risk of overdose and mental health crises, that these risks continued two years after a taper,[16] and that heightened risks of overdose and suicide exist in patients who did not misuse medication and regardless of the pace of the tapering.[17]

Moreover, patients who have been put on opioids by the healthcare system are losing access to healthcare itself: more than 50% of primary care providers state that they are unwilling to take on a prospective patient who uses opioids to manage pain, and 81% are reluctant to do so.[18]

Harms are likely to be borne disproportionately by already marginalized groups. Racially marginalized people, for example, already face additional burdens in receiving pain care by having their pain rated lower by providers and more often being denied pain medication.[19] At least one recent study has found that opioid tapering happens disproportionately to racially marginalized people as well.[20]

As Congress continues to craft legislation to address opioid addiction, it is of utmost importance that the same mistakes not be repeated. We write today to preview our concerns with specific bills introduced in the 116th, 117th, and 118th Congress, as we work with the 118th Congress to craft and improve legislation dealing with prescription opioids and pain treatment.

Strict limits on prescribing

While we appreciate the effort to curb unnecessary prescribing, decisions about appropriate use cannot be made by blanket, one-size-fits-all mandates. An example of this was the provision in the **Addiction Prevention and Responsible Opioid Practices Act (A-PROP) (116th Congress)** that would require the FDA to withdraw market approval for any opioid medication "for which the daily dosage provided for in the approved label exceeds the morphine milligram equivalents per day outlined in the [*CDC Guideline*]," exemplifying the very misapplication the updated 2022 *CDC Guideline* seeks to prevent. Experts in pain and addiction, including some experts involved in developing the *CDC Guideline,* have objected to using numerical thresholds as proxy for quality care.[21] Recent studies suggest that no particular dosage in MME (morphine milligram equivalent) provides an inflection point for increased risk, given that the therapeutic window is highly variable.[22] Further, approaching opioid prescribing thoughtfully is especially important today, given that overdose deaths have continued to rise as prescribing has dropped.

Changes to FDA approvals and activities

The Senate version of the **SUPPORT for Patients and Communities Reauthorization Act (118th Congress: S.3393),** which includes the **FDA Review of Efficacy of EERW Double-Blinds (FREED) of Opioids Act (S. 2737)** and **A bill to require the Secretary of Health and Human Services to prepare a report that outlines a plan for completing a review of approved opioid analgesic drugs that considers the public health effects of such opioid drugs (S. 3557)**, would require the FDA to meet and decide whether to permit use of a research methodology (known as enriched enrollment randomized withdrawal (EERW)) in drug trials involving opioid analgesics. These bills would also require the FDA to reconsider approval for existing medications on the market. Some of our members have led stable and successful lives taking one specific medication for many years, and we are gravely concerned that passage of this bill would result in harm to people who rely on these medications.

A significant limitation in pain treatment is paucity of high-quality research, especially regarding use of opioids long-term for chronic pain. Against that backdrop, outmoding a research methodology – and especially one which studies have found does not appear inferior in assessing opioid efficacy[23] – is unwarranted.

The **Protecting Americans from Dangerous Opioids Act (118th Congress: S. 606)** would also require the FDA to remove existing medications from the market. We have found each patient responds best to a unique combination of treatments. We are seriously concerned for the well-being of seriously ill and disabled Americans if the FDA were to ban a particular treatment plan solely because federal law requires fewer medication formulations in the opioid category.

Opioid taxes

The **Budgeting for Opioid Addiction Treatment Act (118th Congress: LifeBOAT Act, S. 2559)** and the **Safe Disposal of Opioids Act of 2023 (118th Congress: H.R. 5615)** propose a per-milligram stewardship fee to sales of opioid medication. Our greatest concern about these proposals is the disproportionate burden they place on one vulnerable group of patients who require these medications, even if the funds are to be used to expand treatment for another vulnerable group. In states where similar per-milligram fees are imposed as taxes, there is some suggestion that pharmaceutical distributors have narrowed their service areas, and that people have suffered from a lack of access to medication as a result.[24]

While we appreciate the fact that the LifeBOAT Act includes exceptions intended to protect patients from pharmaceutical companies passing costs along to them, given the already burdensome complexities of insurance coverage and prior authorization, we are extremely concerned that the proposed solutions will prove unworkable in practice. In short, patients who qualify for exceptions will likely face untenable administrative hurdles and delays at the pharmacy. Delays leave some patients vulnerable to the illicit counterfeit drug market, potentially worsening the very overdose crisis this bill endeavors to address.

The Safe Disposal of Opioids Act does not include exceptions, and wouwld not protect patients unless they are undergoing cancer treatment or hospice treatment. This bill would have a

dangerous and disproportionate impact on people with disabilities who benefit from opioid medication for any other medical condition.

Remote patient monitoring

The House version of the **Support for Patients and Communities Reauthorization Act (H.R. 4531)**, including the **Remote Opioid Monitoring Act of 2023 (H.R.4093)**, seeks to "improve availability, access, and coverage for remote monitoring for individuals who are prescribed opioids." We recognize the potential of wearable sensors to detect health emergencies (one example being the use of pulse oximeters for COVID-19), though interpreting sensor data can be challenging in medically complex individuals. Remote monitoring, on the other hand, involves storing sensitive data, creating new safety risks. Any device that communicates wirelessly can be identified with an individual: while messages are encrypted using HIPAA-compliant methods, it is not (currently) possible to hide the IP address of the sender and receiver. Remote monitoring adds new safety risks for individuals who take medication with a high "street" value. Thus, we are concerned that H.R.4093 contains no mention of individualized risk assessment or consent, despite potential to significantly infringe on liberty and privacy.

Today, controlled prescriptions are subject to numerous safeguards, including mandatory prescription drug monitoring (PDMP) programs in every state. Those of us in pain treatment already undergo monthly urine drug screens, psychological screening, pill counts, prior authorizations, behavior contracts, and pharmacy lock-ins. Algorithms intended to predict overdose risk, increasingly in use nationwide, are notoriously unsuccessful at identifying who is actually at risk for overdose, often wrongly flagging individuals simply because they require long-term controlled prescriptions.[25] [26] Even with safeguards, more and more physicians have stopped accepting patients with opioid prescriptions,[27] leaving people with disabilities abandoned in grave emergencies.[28]

Adding even more surveillance to the 8-10 million Americans with long-term opioid prescriptions would risk increasing the stigma we already face, and is unlikely to improve an overdose crisis overwhelmingly driven by the illicit and counterfeit drug market,[29] not prescription medication.

Unclear Guidance Regarding "Suspicious" Orders

The **Block, Report, and Suspend Suspicious Shipments Act (118th Congress: H.R. 501)**, which passed the House as H.R. 768 in 2021, requires the Attorney General to promulgate a regulation to flag suspicious orders for controlled substances. Similar to other concerning legislation, the bill does not clearly define what constitutes a "suspicious order." If a seemingly suspicious order is blocked in error, patients could suffer immediate harm from lack of access to necessary medication. To prevent unintended harm, we would request that Congress revise the bill to require a robust definition of what constitutes a suspicious order.

Provisions related to the use of PDMP data

The **Improving Medicaid Programs' Response to Overdose Victims and Enhancing (IMPROVE) Addiction Care Act (118th Congress: S.2481/H.R.4950)**

The IMPROVE Addiction Care Act resembles the California Medical Board's Death Certificate Project, which was redesigned and scaled back after reports that it resulted in unintended harm to patients. Investigations had a chilling effect on appropriate prescribing; overdose deaths actually rose; and only 1% of the doctors marked for investigation after reported overdose events were found to have prescribed unethically.[30] Before rolling out a similar policy nationally, Congress should track outcomes from the revised project in California.

Several bills, including the **Comprehensive Addiction and Recovery Act (CARA) 3.0 (117th Congress: S. 987/ H.R. 4341)** and the **Prescription Drug Monitoring Act of 2021 (117th Congress: S. 889/ H.R. 2344)**, include provisions related to Prescription Drug Monitoring Program (PDMP) data on prescribing and medication use. While we welcome CARA 3.0's omission of strict limits on opioid prescribing, an issue we previously discussed with Congress,[31] we must raise caution about such provisions.

First, provisions from each of these bills would use PDMP data for identification of or intervention for outlier/ high prescribers. Language in CARA 3.0 and the Prescription Drug Monitoring Act requires that law enforcement agencies and prescriber licensing boards be notified about practitioners that "repeatedly fall outside of expected norms or standard practices for the prescribing practitioner's field," but there is no definition of what "expected norms and standard practices" entail. In this case, to prevent unintended harm to patients served by such clinicians, Congress must define "expected norms and standard practices" by reference to comprehensive standards (and not simply an inflexible application of numbers drawn from the *CDC Guideline*). Of note, as required by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act passed in 2018, the Secretary of the US Department of Health and Human Services (HHS) finalized a definition for the term "inappropriate prescribing" in a final rule published in the federal register last year,[32] which encourages thoughtful consideration of a number of factors before arriving at the conclusion that inappropriate prescribing has occurred; some of the factors are not easily identifiable solely through PDMP data. Especially in an environment in which norms about opioid prescribing are in flux, the lack of requirements tied to clear standards is highly problematic.

Second, we are concerned by the requirement in CARA 3.0 that PDMPs proactively inform clinicians about potential misuse, absent instruction about what they should do with that information. First, many common flags of misuse may be inaccurate. For example, people with disabilities often have multiple providers, sometimes requiring travel for specialized treatment; yet having multiple providers is often used to flag people for possible misuse and results in necessary treatment being delayed or denied. Second, without ensuring that providers will address potential misuse with appropriate treatment and referrals, such reports risk subjecting the most vulnerable patients to abandonment. And third, we express concern regarding even de-identified information being distributed, since PDMP data is not covered by the Health Insurance Portability and Accountability Act (HIPAA) and thus lacks assurances of data privacy and security that are provided with regard to other personal medical information.

We ask that Congress include provisions and metrics that consider patient outcomes, to mitigate a further chilling effect on medically necessary prescribing.

SUD treatment

Bills like **CARA 3.0** have the potential to save lives by expanding access to medication for opioid use disorder (MOUD), including mobile clinics in rural areas and removal of prior authorization requirements. However, like several other bills, CARA 3.0 has a provision for funding additional residential treatment facilities. Because people in treatment for or recovery from a substance use disorder (SUD) are protected under the Americans with Disabilities Act, as disability rights organizations we advocate for access to the full range of available treatment options for SUD, and autonomy for people with SUD to make their own decisions about treatment and recovery. Given this provision, we strongly advocate for thoughtful attention to ensuring people with SUD have access to community-based treatment. Our opposition to forced/involuntary treatment includes opposition to institutionalization, and people with SUD often end up in inpatient treatment facilities because community-based treatment is unavailable, insufficient, or inaccessible.

Provider training

The **Safer Prescribing of Controlled Substances Act (117th Congress: S. 2354)** would require practitioners to complete additional training, and would require the Secretary of HHS to evaluate and report on how exposure to such training has changed prescribing patterns of controlled substances. In addition to our previously stated concerns about PDMPs (a topic to be addressed via training), our primary concerns relate to the report on prescribing patterns. First, the bill provides limited details about the required reporting, and no details on what metrics related to prescribing patterns will be measured. It is critical that the report study more than solely number of prescriptions and dosages, and that a reduction of either or both of those measures are not automatically viewed as successes without additional consideration of measures related to patient outcomes. Furthermore, in a 2020 FDA report[33], it was observed that because of the plethora of factors and activities affecting prescribing, the effect of prescriber education cannot be adequately determined. Moreover, since prescriber training was included in the Consolidated Appropriations Act of 2023, and 98% of prescribers already lived in states that require training, we have some concerns that mandating more training will pose one more barrier to discourage clinicians from taking on medication management for the millions of Americans who currently take opioids for pain. [34]

We applaud efforts to expand coverage of non-opioid options as a much-needed policy change, so long as they do not create unnecessary barriers where opioid prescribing is appropriate. The **Non-Opioids Prevent Addiction in the Nation (NOPAIN) Act** (passed into law in the **Consolidated Appropriations Act of 2023**) appears to do this. As the Consolidated Appropriations Act of 2023 requires HHS to study this law's effect on opioid prescribing, we hope to also see reporting on patient outcomes, from pain severity to function and recovery time. While much more must be done to expand coverage for a range of multidisciplinary treatments for chronic as well as acute pain care, we appreciate Congress' willingness to recognize and center the continued importance of pain management.

Finally, during the COVID-19 pandemic, we were heartened to see the Drug Enforcement Agency expand access to telemedicine for Americans with chronic medical conditions including

pain, ADHD, and substance use disorder. In February 2023, the Drug Enforcement Administration proposed rolling back these flexibilities in telemedicine prescribing of controlled substances (Docket #DEA-407 and #DEA-948)**.** NCIL believes these rule changes will have a disproportionate impact on people with disabilities, and Congressional action may be needed to address the resulting harms.

In sum, we, the undersigned organizations representing people with disabilities urge you to take our concerns and recommendations into account, and to work with us in the upcoming legislative session. Please feel free to contact Jessica Podesva (jessica@ncil.org), Director of Advocacy and Public Policy for the National Council on Independent Living.

Sincerely,

Jessica Podesva, J.D.
Director of Advocacy and Public Policy, National Council on Independent Living

Theotis Braddy
Executive Director, National Council on Independent Living

National Pain Advocacy Center

ADA Watch/Coalition for Disability Rights and Justice

Chronic Disease Coalition

The National Chronic Pancreatitis Support Network

Not Dead Yet

Patients Rising

National Coalition for Latinxs with Disabilities

Connective Tissue Coalition

Spa Area Independent Living Services
Hot Springs, AR

Direct Advocacy & Resource Center
Tucson, AZ

Placer Independent Resource Services
Auburn, CA

Service Center for Independent Life
Claremont, CA

California Foundation for Independent Living Centers
Sacramento, CA

Rolling Start
San Bernardino, CA

Silicon Valley Independent Living Center
San Jose, CA

Marin Center for Independent Living
San Rafael, CA

Independence Northwest
Naugatuck, CT

Amputee Coalition
Washington, DC

Florida Independent Living Council
Tallahassee, FL

Aloha Independent Living Hawaii
Pearl City, HI

Progress Center for Independent Living
Forest Park, IL

Stone-Hayes Center for Independent Living
Galesburg, IL

Disability Resource Center
Joliet, IL

Everybody Counts
Merrillville, IL

Illinois Network of Centers for Independent Living
Springfield, IL

Springfield Center for Independent Living
Springfield, IL

The Statewide Independent Living Council of Illinois
Springfield, IL

American Council of the Blind of Indiana
Bedford, IN

Access 2 Independence
Iowa City, IA

Illinois Iowa Center for Independent Living
Rock Island, IA

Southeast Kansas Independent Living Resource Center
Parsons, KS

Center for Accessible Living
Louisville, KY
Stavros Center for Independent Living
Amherst, MA

Boston Center for Independent Living
Boston, MA

Independence Associates
East Bridgewater, MA

Southern Minnesota Independent Living Enterprises & Services
Mankato, MN

Mississippi Coalition for Citizens with Disabilities
Jackson, MS

Disaster and Disability Consultants LLC
Monroe Township, NJ

Access to Independence of Cortland County
Cortland, NY

Tri-Lakes Center for Independent Living
Saranac Lake, NY

Disability Rights and Resources
Charlotte, NC

North Carolina Statewide Independent Living Council
Wilmington, NC

Southeastern Ohio Center for Independent Living
Lancaster, OH

Progressive Independence
Norman, OK

Ability Resources
Tulsa, OK

Disabled United in Direct Empowerment
Ashland, OR

Lane Independent Living Alliance
Eugene, OR

Eastern Oregon Center for Independent Living
Ontario, OR

Independent Living Resources
Portland, OR

Center for Independent Living of Central PA
Harrisburg, PA

Disability Empowerment Center
Lancaster, PA

Pennsylvania Inclusive Higher Education Consortium
Millersville, PA

Disability Pride Pennsylvania
Philadelphia, PA

Pennsylvania Council on Independent Living
Wormleysburg, PA

Able South Carolina
Columbia, SC

Living Hope Wheelchair Association
Houston, TX

Blue Ridge Independent Living Center
Roanoke, VA

Society's Assets
Elkhorn, WI

Access to Independence
Madison, WI

Independence First
Milwaukee, WI

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[1] *See* , Human Rights Watch Report, https://www.hrw.org/sites/default/files/report_pdf/hhr1218_web.pdf
[2] US Center for Disease Control and Prevention. (2019) *CDC Advises Against Misapplication of the CDC Guideline for Prescribing Opioids for Chronic Pain*. https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html
[3] US Department of Health and Human Services. (2019) *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*. https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf
[4] US Food and Drug Administration. (2019) *FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering*. https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes
[5] Centers for Disease Control and Prevention (2022) *Clinical Practice Guideline for Prescribing Opioids for Pain.* https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w
[6] National Public Radio, November 3, 2022, "CDC issues new opioid prescribing guidance, giving doctors more leeway to treat pain," https://www.npr.org/sections/health-shots/2022/11/03/1133908157/new-opioid-prescribing-guidelines-give-doctors-more-leeway-to-treat-pain
[7] Woods C. Prescription opioid utilization patterns in the U.S. FDA public workshop on opioid prescriber education. October 13, 2021. https://healthpolicy.duke.edu/sites/default/files/2021-10/Opioid%20Prescriber%20Education%20Workshop%20Slide%20Deck.pdf
[8] *See* CDC National Vital Statistics, https://www.cdc.gov/nchs/products/databriefs/db457.htm
[9] *See* Lee., B. et al., Systematic Evaluation of State Policy Interventions Targeting the US Opioid Epidemic, 2007-2018. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2776301
[10] Agnoli A, et al., Association of Dose Tapering With Overdose or Mental Health Crisis Among Patients Prescribed Long-term Opioids, https://jamanetwork.com/journals/jama/fullarticle/2782643

[11] James, J.R., Scott, J.M., Klein, J.W. et al. Mortality after discontinuation of primary care-based chronic opioid therapy for pain: a retrospective cohort study. J GEN INTERN MED (2019) 34: 2749. https://link.springer.com/article/10.1007/s11606-019-05301-2

[12] Oliva EM, Bowe T, Manhapra A, 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://www.bmj.com/content/368/bmj.m283

[13] DiPrete BL, Ranapurwala SI, Maierhofer CN, et al. Association of Opioid Dose Reduction With Opioid Overdose and Opioid Use Disorder Among Patients Receiving High-Dose, Long-term Opioid Therapy in North Carolina. *JAMA Netw Open.* 2022;5(4):e229191. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2791566

[14] *See* Mark, T. et al., Opioid medication discontinuation and risk of adverse opioid-related health care events. https://pubmed.ncbi.nlm.nih.gov/31079950/

[15] *See* Glanz J. et al., Association Between Opioid Dose Variability and Opioid Overdose Among Adults Prescribed Long-term Opioid Therapy, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730786

[16] *See* Fenton JJ, Magnan E, Tseregounis IE, Xing G, Agnoli AL, Tancredi DJ. Long-term Risk of Overdose or Mental Health Crisis After Opioid Dose Tapering, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2793293

[17] Larochelle MR, Lodi S, Yan S, Clothier BA, Goldsmith ES, Bohnert ASB. Comparative Effectiveness of Opioid Tapering or Abrupt Discontinuation vs No Dosage Change for Opioid Overdose or Suicide for Patients Receiving Stable Long-term Opioid Therapy. *JAMA Netw Open*. 2022;5(8):e2226523. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2795159

[18] *See, e.g.* Gavin, K., Patients who take opioids can't get in the door at half of primary care clinics, https://labblog.uofmhealth.org/industry-dx/pain-patients-who-take-opioids-cant-get-door-at-half-of-primary-care-clinics, January 25, 2021, citing Lagisetty, P.; Macleod, C.; Thomas, J.; Slat, S,' Kehne, A, Heisler, ; Bohnert, A; Bohnert, K, M.[b,e,f]. Assessing reasons for decreased primary care access for individuals on prescribed opioids: an audit study. PAIN: May 2021 - Volume 162 - Issue 5 - p 1379-1386 https://pubmed.ncbi.nlm.nih.gov/33230009/ and Lagisetty P, 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. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2737896

[19] *See, e.g.*, Hoffman, K. et al., Racial bias in pain assessment and treatment recommendations, and false beliefs about biological differences between blacks and whites, https://pubmed.ncbi.nlm.nih.gov/27044069/; Lee, P., et al., Racial and ethnic disparities in the management of acute pain in US emergency departments: Meta-analysis and systematic review, https://pubmed.ncbi.nlm.nih.gov/31186154/

[20] *See* Fenton, J. et al, Trends and Rapidity of Dose Tapering Among Patients Prescribed Long-term Opioid Therapy, 2008-2017, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2755492

[21] *See* Kertesz, S et al. An opioid quality metric based on dose alone? 80 professionals respond to NCQA (March 22, 2017) https://medium.com/@StefanKertesz/an-opioid-quality-metric-based-on-dose-alone-80-professionals-respond-to-ncqa-6f9fbaa2338

[22] Yu-Jung, J. et al. "Performance of the Centers for Medicare & Medicaid Services' Opioid Overutilization Criteria for Classifying Opioid Use Disorder or Overdose" JAMA February 12, 2019 Volume 321, Number 6. https://jamanetwork.com/journals/jama/fullarticle/2724180

[23] Furlan A, Chaparro LE, Irvin E, Mailis-Gagnon A. A comparison between enriched and nonenriched enrollment randomized withdrawal trials of opioids for chronic noncancer pain. Pain Res Manag. 2011 Sep-Oct;16(5):337-51. https://pubmed.ncbi.nlm.nih.gov/22059206/

[24] *See* Gliadkovskaya, "Patients struggle to access prescription opioids after New York tax drives away suppliers," *Fortune*, November 15, 2020. https://fortune.com/2020/11/15/new-york-state-tax-opioids-prescription-pharmacies-supply/

[25] Oliva, Jennifer, Dosing Discrimination: Regulating PDMP Risk Scores (January 18, 2021). 110 California Law Review 47 (2022), Available at SSRN: https://ssrn.com/abstract=3768774 or http://dx.doi.org/10.2139/ssrn.3768774

[26] *See* Yu-Jung, J. et al. "Performance of the Centers for Medicare & Medicaid Services' Opioid Overutilization Criteria for Classifying Opioid Use Disorder or Overdose" https://pubmed.ncbi.nlm.nih.gov/22059206/

[27] Lagisetty, P, et al. *Assessing reasons for decreased primary care access for individuals on prescribed opioids, an audit study*, PAIN (Nov. 11, 2020), https://pubmed.ncbi.nlm.nih.gov/33230009/. *See also* https://labblog.uofmhealth.org/industry-dx/pain-patients-who-take-opioids-cant-get-door-at-half-of-primary-care-clinics (Jan. 25, 2021).

[28] Keegan Hamilton, "This Couple Died by Suicide After the DEA Shut Down Their Pain Doctor," *Vice*, November 30, 2022. https://www.vice.com/en/article/wxnyb9/dea-fentanyl-doctor-patient-suicide

[29] Walley AY, Bernson D, Larochelle MR, Green TC, Young L, Land T. The Contribution of Prescribed and Illicit Opioids to Fatal Overdoses in Massachusetts, 2013-2015. *Public Health Reports*. 2019;134(6):667-674. doi:10.1177/0033354919878429

[30] *See* Clark, "California Medical Board to Revise Dreaded Death Certificate Project," November 17, 2020, https://www.medpagetoday.com/practicemanagement/medicolegal/89740

[31] *See* Sen.Gillibrand on her bill with former Sen. Gardner, https://medium.com/@gillibrandny/i-hear-you-and-i-want-to-get-my-bill-on-opioids-right-1664f8b17f87

[32] Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 85 Fed. Reg. 33796, (1/19/2021).

[33] US Food and Drug Administration. (2020). *Methods for Evaluating the Opioid Analgesic Risk Evaluation and Mitigation Strategy.* https://www.fda.gov/media/143549/download

[34] US Food and Drug Administration Convening, Public Workshop on Prescriber Education (background materials) (co-sponsored by Duke Margolis Center for Health Policy), October 13, 2021 https://healthpolicy.duke.edu/events/fda-public-workshop-opioid-prescriber-education